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The Industrial Internet of Things Importance in Improving Pharmaceutical Operations

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Abstract: Industry 4.0 is revolutionizing the manufacture of pharmaceuticals through the incorporation of the Industrial Internet of Things (IIoT). The IIoT enhances process efficiency, product quality, and regulatory compliance by enabling intelligent production equipment, automated quality control, and real-time supply chain traceability. This review presents the latest technological developments and practical industrial applications to examine how the IIoT enhances manufacturing precision, data traceability, and operational reliability in pharmaceutical production. Key enablers, including predictive maintenance, electronic batch records, and blockchain for logistics, are evaluated for efficiency and compliance potential. The paper has also highlighted key challenges such as cybersecurity vulnerabilities, interfacing with legacy equipment, and inertia to digitalization. It also examines the next up-and-coming trends, including digital twins, edge computing, and 5G infrastructure that will power new levels of industrial innovation. The results offer an in-depth insight into the disruptive power of the IIoT and suggest strategic directions for key stakeholders pursuing data-driven, compliant, and globally responsive pharmaceutical operations.

Keywords: digital transformation, Industrial Internet of Things (IIoT), pharmaceutical manufacturing, real-time monitoring, regulatory compliance

1. Introduction

Pharma is innovation and control coming together in one place: science needs to be controlled, after all. The fourth industrial revolution (Industry 4.0) in recent years has changed the operational models by cyber-physical systems (CPS), cloud computing, intelligent automation, etc. [1]. At the center of this evolution is the Industrial Internet of Things (IIoT), a system of interrelated devices that can collect, send, and act on data in real time.

Pharma operations, which are typically risk averse in embracing disruptive technologies with regulatory unknowns at the helm, are feeling the heat to modernize. The COVID-19 outbreak brought out the deficiencies in the global supply chain, limitations of conventional quality assurance systems, and prospective favor for operational transparency [2]. In reaction, for example, IIoT tech provides real-time process optimization, automatic compliance, and leading-edge risk management via smart sensors and blockchain-secured data.

While other industries have rapidly adopted new digital technologies, the pharmaceutical sector remains slower to implement the IIoT because of complex legacy systems and strict regulatory constraints. With a few exceptions, studies investigating Industry 4.0 and automation in manufacturing have yet to provide an overview of how the IIoT specifically improves efficiency, traceability, and compliance within pharmaceutical production. This difference in previous research demands a clearly focused investigation on how IIoT solutions can reconcile innovation with stringent regulatory requirements.

The main purpose of this paper is to examine the impact of the IIoT on pharmaceutical production process optimization, quality control, and regulatory compliance. Additionally, we hope to identify the key challenges from cybersecurity to data integration and regulatory ambiguity and call out emerging tech trends like digital twins, edge computing, or such that would become reality with 5G connectivity.

This paper uses a qualitative literature review approach and consolidates recent academic and industry-driven studies (between 2015 and 2025). Through melding theoretical knowledge and real-world investigations, the paper achieves comprehensive insight into how IIoT technologies lead to pharmaceutical operations and processes that are data-driven, adaptive, and compliant.

The adoption of the IIoT in pharmaceutical production has garnered increased research attention over the last decade owing to its potential for real-time analytics, automation, and improving adherence to regulatory standards. Lee et al. [2] suggested a CPS architecture for Industry 4.0 manufacturing systems with a focus on sensor-based decision-making and real-time control loops. While not pharma-specific, their work has had a profound impact on how smart manufacturing concepts are implemented in regulated settings, especially where traceability of data and integrity of product are of high importance.

Expanding on this, Kan et al. [3] examined IIoT's implementation specifically in pharma manufacturing, highlighting its potential to reduce batch rejection rates and improve Good

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Manufacturing Practice (GMP) compliance. Their article provided empirical evidence from case implementations of smart sensors and predictive maintenance algorithms. However, the authors also noted continued shortcomings in integrating the IIoT with installed enterprise resource planning (ERP) systems, a bottleneck in the majority of pharma firms.

Another notable contribution by Botene et al. [4] examined the use of blockchain-enabled IIoT platforms using Distributed Ledger Technologies (DLTs) for pharma logistics, more precisely vaccine distribution. Their findings indicated that the integration of the IIoT with DLTs not only increases transparency but also minimizes the entry of counterfeit medicines into the supply chain, an issue of concern for both the World Health Organization and the US Food and Drug Administration (FDA).

In contrast, Abosata et al. [5] adopted a more critical tone, discussing the cybersecurity vulnerabilities introduced by the IIoT into pharma. Although they cited operational advantages, they cautioned that improper network device configuration would result in regulatory noncompliance or, worse, exposure of sensitive intellectual property. Their call for cybersecurity-by-design has since been echoed in the FDA draft computer software assurance guidance.

Finally, Kalsoom et al. [6] conducted a systematic review of 108 peer-reviewed studies on IoT adoption in the manufacturing Industry 4.0. They identified key drivers, such as improving operational efficiency and productivity through real-time monitoring, as well as barriers, including significant upfront costs and human resistance to technology adoption.

All of which indicates that while the pharmaceutical industry has lagged other manufacturing industries in its adoption of the IIoT, this momentum is changing. Literature coalesces on one thesis: IIoT adoption is not just a technological revolution but a strategic necessity for firms that want to remain competitive in an increasingly digital and regulated global economy.

More recent publications have reinforced this concept. Ale et al. [7] submitted a systematic review specifying that IIoT implementation within pharma is increasing with pandemic-driven digitalization impulses. Ikpe et al. [8] also emphasized the fusion between the IIoT and Industry 4.0 in smart factory settings, noting remaining interoperability and workforce upskilling challenges.

However, despite such advances, deployment of the IIoT in pharma remains fragmented and inconsistent, suggesting there is still a gap to be closed between technology readiness-potential "innovations," compared with regulatory or operational readiness.

This article provides a comprehensive overview of IIoT's role in optimizing pharmaceutical operations. It begins with a review of relevant literature contextualizing IIoT in pharma and then examines its applications in manufacturing, regulatory compliance, and logistics. Key implementation challenges are analyzed, followed by a discussion of emerging technological frontiers. The paper concludes with strategic recommendations for stakeholders aiming to optimize the potential of IIoT technologies.

The remainder of this paper is structured as follows. Section 2 explores how the IIoT transforms pharmaceutical manufacturing through continuous process monitoring, predictive maintenance, and automated batch control. Section 3 focuses on IIoT's role in enhancing quality control and regulatory compliance through electronic batch records (EBRs), blockchain-enabled traceability, and continuous process verification. Section 4 analyzes supply chain optimization using IIoT-based systems for cold chain management, smart inventory, and logistics automation. Section 5 identifies the main obstacles to IIoT adoption—cybersecurity, integration with legacy systems, and regulatory uncertainty—alongside practical mitigation strategies. Section 6 discusses emerging developments such as digital twins, 5G networks, and interoperability standards that define the future of the IIoT in pharmaceuticals. Finally, Section 7 concludes with a synthesis of findings and outlines recommendations for stakeholders to ensure sustainable digital transformation in the pharmaceutical sector.

2. IIoT in Pharmaceutical Manufacturing

Industry 4.0 represents a recent trend in pharmaceutical processing, integrating advanced technologies to create real-time data-driven systems. This marks a shift from traditional batch synthesis to adaptive, data-centric manufacturing. This conversion addresses some of the critical industry requirements, that is, increased regulation compliance, operational flexibility, and consistent product quality.

2.1. Continuous process monitoring and improvement

Real-time reporting thanks to the IIoT enables environmental and process control that was not possible with manual approaches. Monitoring sensors installed in manufacturing equipment keep track of criticalities such as temperature, humidity, pressure, and vibration. Such inputs are processed and make decisions in real-time using edge computing devices or the cloud.

The worldwide scientific and engineering community has recently felt its responsibility for the environment and public health in dealing with environmental pollution. This paper introduces an IoT system aimed at continuous environmental monitoring for the rapid identification of problems and immediate undesirable phenomena mitigation. Regulatory agencies have access to pollution data in real time, which can be used for timely intervention. This method is good for maintaining public health and mitigating the possibility of natural disasters due to environmental imbalances [9]. Recent research by Chen et al. [10] further confirms that continuous, data-driven manufacturing enhances process stability and purification efficiency in pharmaceutical systems.

2.2. Predictive maintenance and asset management

Conventional maintenance tends to be based on scheduled or reactive routines, both of which can lead to expensive equipment failure or unwarranted downtime. The IIoT moves beyond this paradigm with predictive maintenance, wherein historical and real-time data from equipment are run through artificial intelligence (AI) models to forecast likely equipment failure or servicing needs [11].

Novartis applied IIoT predictive analytics at its Stein plant in Switzerland, reducing unplanned maintenance events by 25%. New evidence [2, 12] suggests that combining IIoT with edge intelligence can further minimize latency in predictive models, improving real-time reliability.

2.3. Batch release and automated process control

The IIoT enables automatic, closed-loop control systems that adjust parameters in real time to maximize yield and minimize error. It supports near real-time batch release, key to continuous manufacturing. At Janssen Pharmaceuticals, inline spectrometers and IIoT dashboards contributed to reducing batch cycle times by 40% [13].

Emerging implementations show that such automation can be combined with 5G edge platforms to implement sub-second process correction, which will bring us closer to fully adaptive manufacturing systems [10].

3. Enhancing Quality Control and Regulatory Compliance

Pharma operations revolve around regulatory compliance and quality control, two of the most critical and resource-intensive tasks imaginable. The tight regulation from the likes of the US FDA and European Medicines Agency (EMA) means that meticulous recording, tracking, and monitoring are necessary in real time. Technologies such as the IIoT offer a means to address these by using automated tracking, data integrity tools, and predictive analytics.

3.1. Electronic batch records (EBRs) and data integrity

With IIoT solutions, EBRs are fully digitized, providing pharmaceutical manufacturing organizations with the ability to automatically gather time-stamped and validated data during each phase of production. This digitalization not only reduces the workload of regulatory audits but also reaffirms compliance with ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate plus Complete, Consistent, Enduring and Available) principles. Through the use of IIoT sensors and connected devices, pharmaceutical companies can achieve real-time data collection directly from manufacturing equipment, which means no more manual transcription errors and complete compliance with tough data integrity standards required by regulators [14].

As shown in Figure 1, the IIoT architecture integrates physical manufacturing assets with digital intelligence. Each layer, from sensors to enterprise systems, serves a distinct function in enhancing operational reliability, improving transparency, and ensuring regulatory compliance throughout the production lifecycle.

This high-level architecture demonstrates the integration among layers of sensing, edge computing, and cloud analytics to enable real-time decision support in pharmaceutical production. Data produced by these pieces of production equipment and sensor hardware travels up to be aggregated and analyzed, while control commands travel down as their parameters are adjusted in real time. It provides traceability, quality control, and regulatory compliance by means of real-time monitoring, electronic batch recording, and alarms.

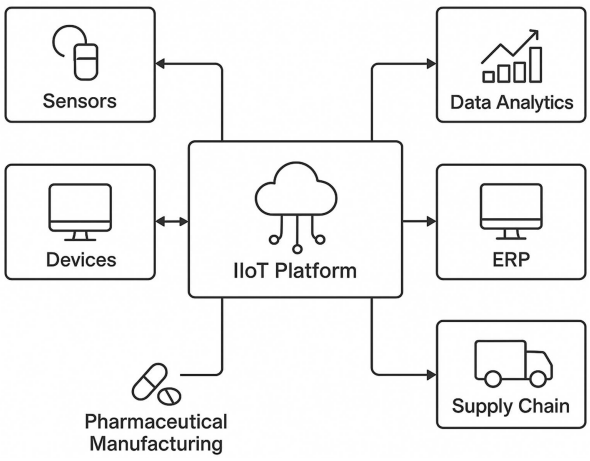

Figure 1. Conceptual architecture of an IIoT-enabled pharmaceutical manufacturing system

Legend: Data flows: upward for decision-making and downward for control actions. Edge analytics: Reduces latency and minimizes reliance on centralized cloud computing. Compliance and QA layers: Directly linked to enterprise systems for audit and reporting.

For instance, GSK implemented IIoT-powered EBRs on several factory sites, reducing batch record review time by 60% and significantly lowering deviations caused by manual entry errors [15]. Synchronizing machine data and operator activity in real-time enabled effortless audit trails and reduced compliance burden.

3.2. Blockchain for drug traceability and anti-counterfeiting

Fake drugs, which cause more than $200 billion in annual losses in the global pharmaceutical market, pose a serious threat to public health and undermine confidence in quality standards [16]. When integrated with blockchain platforms, the IIoT can offer tamper-proof, real-time records of a drug's entire lifecycle—from sourcing raw materials to final delivery to the end user.

One prominent use case was Moderna's vaccine supply chain that used IoT sensors for tracking temperatures and a blockchain ledger for secure serialization and chain-of-custody tracking of vaccines for COVID-19 [17]. The hybrid solution enabled the FDA's Drug Supply Chain Security Act (DSCSA) compliance and enhanced public confidence in the authenticity and safety of the vaccine.

3.3. Continuous Process Verification (CPV)

Traditional quality control often relies on post-manufacturing sampling, which can lead to delays and the risk of undetected deviations. The IIoT enables Continuous Process Verification (CPV) by collecting and analyzing production data in real time, in accordance with the International Council for Harmonisation (ICH) Q8–Q11 guidelines on Quality by Design (QbD) and process validation.

IIoT sensors were used to implement a CPV system in aspirin manufacturing at Bayer's Leverkusen site, which led to a 30% reduction in quality deviations and faster regulatory reporting [18]. Quality assurance (QA) teams could intervene immediately upon detection of out-of-spec parameters using real-time dashboards, without shutting down production, while ensuring product integrity.

4. The Role of IIoT in Supply Chain Optimization

The pharma supply chain is notoriously complicated, stretching across a global network of raw material suppliers, manufacturers, distributors, and retailers. The results of disruption, tardiness, or disobedience are so grave. The IIoT is the heart of converting these traditionally siloed systems into intelligent, wired, and trackable ecosystems.

Table 1 summarizes the key operational differences between conventional pharmaceutical processes and those enhanced through the IIoT. The comparison highlights how digital connectivity enables real-time control, predictive maintenance, and automated compliance across the production lifecycle.

Table 1. Comparison between traditional and Industrial Internet of Things–enhanced pharmaceutical processes

Dimension	Traditional approach	IIoT-enhanced approach
Process monitoring	Periodic manual checks	Continuous real-time monitoring via networked sensors
Maintenance strategy	Reactive or scheduled maintenance	Predictive and condition-based maintenance using data analytics
Batch documentation	Paper-based batch records	Electronic batch records (EBRs) with time-stamped digital data
Quality assurance	Post-production sampling	Continuous Process Verification (CPV) with inline quality monitoring
Supply chain visibility	Fragmented, limited to ERP updates	End-to-end visibility with IoT tracking, RFID, and blockchain
Regulatory compliance	Manual documentation, prone to human error	Automated compliance reporting with audit-ready digital trails
Response time	Hours to days	Real-time alerts and automated process adjustments
Data integration	Siloed systems with minimal interoperability	Integrated systems using open protocols (e.g., OPC UA, MQTT)

4.1. Tracking the cold chain for temperature-sensitive products

Maintenance of strict environmental conditions is a requirement that cannot be relaxed for biologics, vaccines, and cell and gene therapies. Temporary fluctuations in temperature or humidity are sufficient to render products ineffective or unsafe. IIoT sensors are now becoming central to the cold chain integrity by monitoring real-time critical variables along the storage and distribution chain lifecycle.

A notable high-impact example comes from the distribution of Pfizer-BioNTech COVID-19 vaccines, where IIoT-enabled temperature loggers continuously monitored the required -70°C storage conditions during transport. These sensors were connected through GPS-based cellular networks and automatically triggered alerts in the event of temperature deviations, enabling timely intervention before any spoilage occurred [19].

4.2. Intelligent inventory management and demand forecasting

The traditional approaches to inventory management result in overstocking, wastage, or stock-out, especially for costly or short shelf-life medicines. The IIoT offers a smart solution through Radio Frequency Identification (RFID) tagging, Real-Time Location System, and AI-driven forecasting software.

Johnson & Johnson implemented a smart inventory system designed to span its European warehouses using IIoT sensors and machine learning (ML) algorithms to optimize inventory levels. Thus, inventory holding costs were reduced by 18% and service-level agreements with healthcare providers increased by 22% [20].

These systems also facilitate adherence to the serialization requirements of the EU Falsified Medicines Directive through real-time monitoring of the movement and authenticity of every single unit of product.

4.3. Logistics and route optimization with AI

AI + IIoT allows adaptive logistics where carriers, transport routes, and delivery times are dynamically optimized depending on weather conditions, traffic, or border congestion. It reduces costs and ensures patients and providers receive medicine quicker, more consistently.

Roche Diagnostics collaborated with a logistics technology company to implement a cloud-based IIoT logistics solution throughout Latin America. The platform used real-time meteorology and customs information to redirect the delivery of essential oncology medication during the COVID-19 pandemic, preventing customs delays and temperature excursions [21].

5. Issues and Solutions in IIoT Adoption

Though it holds huge promises for change, the adoption of the IIoT in the pharma business is fraught with serious challenges. These range from technical, organizational, regulatory, and cost factors. Lacking planning and stakeholder engagement, even the most advanced IIoT systems cannot possibly deliver their intended benefits.

5.1. Cybersecurity and data privacy risks

A significant cybersecurity challenge is the expanded attack surface provided by IIoT devices, many of which are connected to networks or clouds or edge platforms. Cybersecurity breaches in pharmaceuticals are particularly severe, as they involve sensitive patient data, proprietary compounds, and diagnostic information. A breach can lead to significant financial and reputational damage.

Alcaraz and Zeadall [22] emphasized the importance of cybersecurity-by-design across IIoT ecosystems and recommended the adoption of end-to-end encryption, network segmentation, and real-time anomaly detection solutions. The FDA's 2023 Draft Guidance on Cybersecurity in Medical Devices and the European Union Agency for Cybersecurity have outlined the importance of secure-by-default IoT architectures in life sciences.

Recommended Solution: Multilevel security controls are implemented, followed by compliance with ISO/IEC 27001 and frequent red team penetration tests. Pharma companies are also looking to zero trust architecture to make it all about identity and behavior—not location or role.

5.2. Integration with existing legacy systems

In the life sciences, most drug plants are filled with legacy systems—often decades old—that were never intended to support any real-time communications and analytics. This makes the introduction of the IIoT into such an environment demanding

in terms of retrofitting, middleware development, and interface standardization, especially if enterprise systems such as Manufacturing Execution System, Laboratory Information Management System, or ERP do not offer common data models or application programming interfaces.

Best practice solution: Use hybrid infrastructure solutions with edge analytics and cloud-based analytics to reduce disruption during the shift. Vendor-neutral communication protocols like Open Platform Communications Unified Architecture (OPC UA) facilitate the integration of both new IIoT components and older Supervisory Control and Data Acquisition or Programmable Logic Controller systems.

5.3. Regulatory uncertainty and compliance complexity

Regulatory authorities are increasingly open to digital transformation, but there is still uncertainty on how data generated by the IIoT would be validated, stored, and displayed with existing regulations such as 21 CFR Part 11 or Annex 11 of the EU GMP.

Additionally, real-time data gathering obscures the traditional functions of batch release, quality review, and documentation processes to develop tension between innovation and compliance.

Recommended Solution: Engagement of regulatory bodies in the design of IIoT systems at an early stage. Pilot studies, co-designed with regulatory sandboxes such as those facilitated by the EMA or the UK MHRA Innovation Office, can also provide a space to test ideas and gather feedback before a wider roll-out.

5.4. Resistance to change in organizations

Implementing IIoT also requires a cultural transformation—shifting from relying on printed spreadsheets in the boardroom to embracing real-time, data-driven decision-making. Resistance often stems from fears of job loss, low levels of digital literacy, and distrust in the decision-making capabilities of algorithms.

Recommended Approach: Invest in the development of the workforce, in programs for digital literacy, change management, as well as cross-functional training. "Digital champions" programs have been adopted by companies such as Sanofi, where trained IIoT adopters are embedded in each department to facilitate the transition and offer peer support [23].

5.5. High capital outlay and ROI issues

The upfront investment required to install the IIoT infrastructure (sensors, gateways, data analytics platform, and cybersecurity solutions) can be significant. This presents a significant challenge to the small and medium-sized pharma companies.

Recommended Action: Offer government and trade association economic incentives, tax breaks, and public–private partnerships to continue driving digital transformation. The US Advanced Manufacturing Office and the European Commission's Digital Europe Program have launched funding opportunities to accelerate the adoption of IIoT technologies in the pharmaceutical, biotechnology sectors.

6. Future Opportunities and Developments in IIoT

As the IIoT gains maturity, pharma is reaching out into new areas that can stretch smart manufacturing, real-time analysis, and end-to-end system integration once again. This section explores emerging paradigm-shifting technologies—such as digital twins, 5G, and universal interoperability—that are set to transform the pharmaceutical industry.

6.1. Process simulation and optimization using digital twins

AstraZeneca piloted a digital twin strategy on one of its biologics manufacturing lines and realized a batch yield enhancement through the optimization of virtual agitation and aeration parameters [24]. The strategy utilized real-time data streams from fermenters and downstream processing equipment for adjusting parameters in real time.

Digital twins also facilitate regulatory submissions since simulation outcomes derived from validated sensor information may increase process understanding and substantiate claims for quality consistency per ICH Q12 guidance.

Furthermore, live IIoT data continues to be leveraged for training AI/ML models used initially for predictive analytics and now increasingly for autonomous process control. Siemens' MindSphere platform, among others, is pushing pharma manufacturers to develop and run ML algorithms based on flows of IIoT sensor data—for higher production efficiency and early discovery of faults. These integrations represent the transition to smart, self-adaptive producing systems based on this never-ending data feed.

6.2. 5G and edge computing for real-time responsiveness

Traditional IIoT systems are prone to leveraging cloud infrastructure, which can add latency and limit responsiveness—especially in pharmaceutical operations that are critical in terms of timeliness. The introduction of 5G networks and edge computing offers the solution by enabling ultra-low latency communications and local data processing.

Merck partnered with Ericsson in 2023 to introduce a 5G-based IIoT platform in its Darmstadt plant. This allowed edge devices to process data from cleanroom conditions and even from laboratory instrumentation locally, offloading the network and facilitating split-second response to out-of-spec readings [25].

5G also supports massive device connectivity, which is critical for IIoT use cases involving thousands of sensors in multi-site global operations. With AI at the edge, this technology enables autonomous, intelligent manufacturing cells.

6.3. Scalable architectures and interoperability standards

One of the most formidable barriers toward the widespread adoption of the IIoT is the lack of universal interoperability standards. Suppliers try to impose on users "closed, proprietary" environments where integration can be expensive and upgrading is a risky business. Pharmaceutical firms and regulatory authorities are pushing more and more for open, modular, and scalable IIoT architectures to overcome this.

Minimum requirements are:

1) OPC UA: A comprehensive industry-backed, platform-agnostic standard for security, reliable exchange of data between industrial systems and devices.
2) Health Level Seven Fast Healthcare Interoperability Resources (HL7 FHIR): Though designed specifically for healthcare information, it is being applied now to the pharma industry for

linking manufacturing information with clinical and post-marketing surveillance reports.
3) International Society of Automation Standards 88 and 95 (ISA-88/ISA-95): Control system enterprise integration standards that are essential in batch manufacturing environments.

The BioPhorum Operations Group initiated an industry-wide collaborative project to develop a reference architecture for plug-and-play IIoT modules, in order to minimize validation burdens and speed up deployment in regulated environments.

7. Conclusion

This move affects not only the technological upgrade but also changes the way that medications are created, produced, and distributed in the pharmaceutical sector. This study integrated recent industrial practices and research results from 2015 to 2025 and assessed the impact of interlinked digital systems on operational efficiency, product quality, and regulatory compliance. The results suggest that with the intelligence of smart sensors, predictive data analytics, and blockchain-based technologies, production is more precise, batch release is much faster, and supply chains become transparent. These achievements are in line with the objectives of those such as data integrity, risk reduction, and continued process verification set out by international regulatory bodies. The review also identified continued challenges, including cybersecurity weaknesses, the problem of integrating current digital tools with old systems, and the necessity for coordinating global rules. Key enablers for real-time decision-making and for adapting manufacturing included emerging technology (such as digital twin simulation, 5G wireless connectivity, and edge computing products. To enable full realization of the digital transformation in pharmaceutical operations, we need to work together to develop interoperable frameworks, employees' digital skills, and an open dialogue with regulators. At the end, whether the transition of the pharmaceutical industry utilizing the IIoT is successful or not will hinge on both whether technology support and if we all gather around to make sure there is a way how innovation, compliance, and patient safety can move together under one scheme.

Ethical Statement

This study does not contain any studies with human or animal subjects performed by any of the authors.

Conflicts of Interest

The authors declare that they have no conflicts of interest to this work.

Data Availability Statement

The data that support this work are available upon reasonable request to the corresponding author.

Author Contribution Statement

Wesam Fatafta: Conceptualization, Methodology, Validation, Formal analysis, Data curation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration. **Konstantin Koshechkin:** Investigation, Supervision. **Aseel Alshoraihy:** Software, Validation, Investigation, Writing – review & editing, Visualization. **Najm Al-dain Al-sameeai:** Methodology, Resources. **Ali Ibraheem:** Conceptualization, Software, Resources, Visualization. **Mohammad Nazeer Masal:** Data curation. **Abdulwahid Mohammed:** Writing – original draft, Project administration.

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