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Digital twin in pharma manufacturing enhancing QMS with virtual simulations

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ABSTRACT

Digital twin technology is swiftly becoming a groundbreaking advancement in pharmaceutical manufacturing, propelling the sector toward Pharma 4.0. A digital twin serves as a dynamic, digital replica of physical systems, facilitating continuous surveillance, modelling, and optimization of intricate processes. This technology tackles essential challenges in the medicinal products sector, including the preservation of data integrity, the assurance of product quality, the enhancement of process oversight, and the fulfilment of rigorous regulatory standards. Utilizing IoT, the use of AI, and big data statistical analysis, digital twins improve decision-making, facilitate predictive maintenance, and reduce variability in production.Digital twins provide many advantages, as shown in several case studies from different industries. In the midst of the COVID-19 pandemic, Pfizer used digital twin models to speed up vaccine production, while Novartis and GSK used facility-wide digital replicas to enhance quality assurance, decrease failures, and increase batch uniformity. These achievements prove that digital twins may improve efficiency, follow regulations, and ultimately benefit patients.

There are obstacles to adoption, notwithstanding its advantages. Problems with data harmonization, cybersecurity, and the intricacy of complying with rules like FDA 21 CFR Part 11 persist as major obstacles. To get around this, pharmaceutical firms need to beef up their cybersecurity, establish consistent data governance practices, and establish a scalable IT infrastructure. If digital transformation is to be a success, it is equally critical to encourage a culture of constant improvement and cooperation across departments.In the future, digital twins will be much more powerful when combined with blockchain technology to provide supply chain visibility, internet of things (IoT) to track metrics in real-time, and deep learning to boost quality continuously. The establishment of uniform standards and best practices will need close cooperation between pharmaceutical companies, technology suppliers, and regulatory bodies. In the end, digital twin technology might completely change the way pharmaceuticals are made. It could lead to better healthcare solutions that are safer, more effective, and focused on the patient. Plus, it could assure conformance and operational excellence.

INTRODUCTION

Digital Twin technology originally appeared in production and engineering with Industry 4.0, and has since proven transformative in health research. A digital twin is an exact replica of an existing system or object that can mimic its behaviour in a virtual setting. They are computer models of physical infrastructure or processes that can respond to changes in the actual environment by interacting with data collected in real time.Without interfering with actual production, these twins are used in the pharmaceutical industry to model, test, and

optimize anything from bioreactor dynamics to control systems.By translating the patient's bodily attributes and physical changes to the digital world, a virtual representation of the patient is produced. One of the most crucial medical concepts is accurate diagnosis and adherence to patient-appropriate treatment protocols, which this technology provides creative and conclusive answers, Studies conducted in the pharmaceutical industry and customized medical sectors also demonstrate the utilization of technology [1].The Digital Twin is a digital clone of a physical system created by modelling its state, gathering data through sensors, and reflecting it in digital media. Digital Twins bridge both the digital and physical universes by allowing us to comprehend both historical and contemporary processes and make judgments for the future[2].In pharmaceutical manufacturing, digital twins are used to mimic and optimize operations, improve product quality, and increase overall operational efficiency. Create a computerized reproduction of a manufacturing process, including equipment, materials, and ambient variables. Digital transformation has enormous benefits for the pharmaceutical business, which faces strict regulatory constraints, complicated production processes, and a fundamental need for quality assurance. The sector confronts particular issues, including sustaining cold chains, ensuring product traceability, preventing counterfeiting, and managing complicated worldwide distribution networks. The growing use of personalized medicine and biologics complicates pharmaceutical supply chains. Implementing digital twins can help the pharmaceutical business increase operational efficiency, product quality, and patient outcomes[3].

Furthermore, it is critical to identify new revenue streams, reduce waste, costs, and energy use, perform predictive maintenance on manufacturing processes, improve quality and customer satisfaction, track each product from production to finish, enable new business models, reduce time to market, and finally increase part manufacturing productivity through digital twin technology in pharmaceutical manufacturing. An important advantage of this upgraded digital twin technology is the capacity to provide more than just an exact replica. It may give additional benefits on account of digital twins, which are not accessible for physical assets.[4].

Design of digital twin for manufacturing:

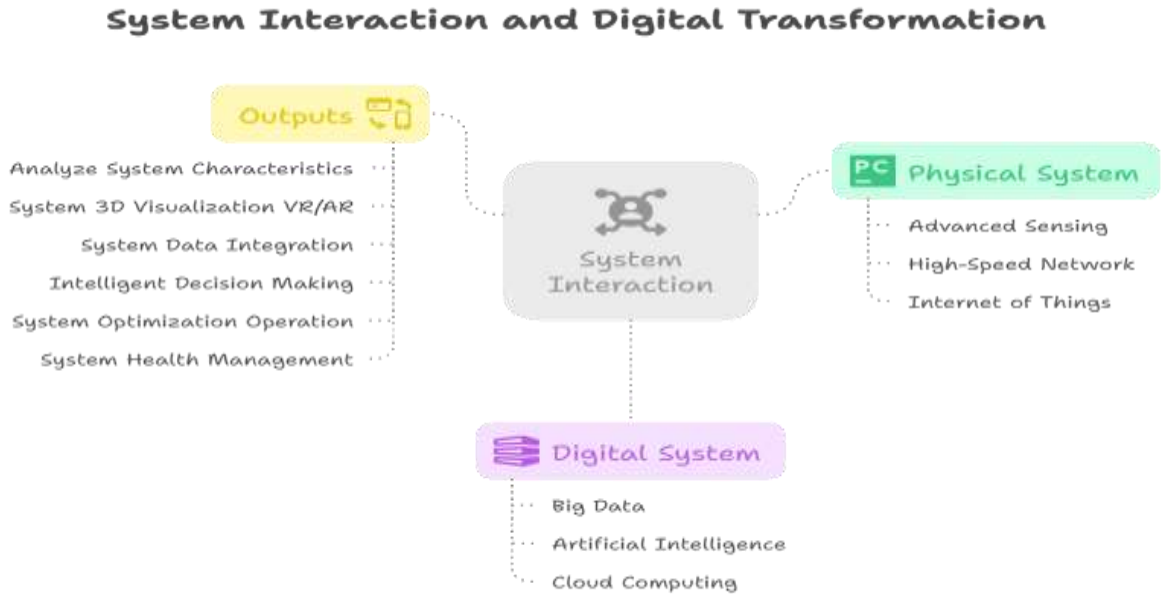

Fig 1: digital twin in manufacturing

The implementation of digital twins in a production system can be divided into three phases.

Through validation and testing performed on a digital twin during the system design phase, inefficiencies may be rapidly identified and the viability of physical manufacturing solutions evaluated. Now is the moment to use a digital twin to keep tabs on the production system's health and make adjustments as needed. As a result, problems may be found before they become serious, failures can be anticipated, and the system can run more smoothly.[5].

In the system setup/reconfiguration phase, the digital twin-based configuration is intended to allow for the semi-physical simulation validation of manufacturing system performance. This phase usually entails creating a virtual model based on the physical system's standards, such as shape, material qualities, and operating circumstances. Once built, the digital twin can be used to replicate system behaviour under a variety of scenarios, such as modifications to input parameters or the addition of additional components. During this stage, the virtual model can also be utilized to uncover potential problems and weaknesses in the physical structure before they happen[6].

The ability to make changes to the virtual model's online parallel management and transmit those suggestions back into the real-world production system is a key enabling technology in system operation. During this phase, DT can be utilized to continuously monitor and optimize the functioning of industrial processes. This can assist producers to discover and rectify reduce inefficiencies, increase production efficiency, and head off potential problems before they cause downtime[6],[7].

Pros and cons of digital twin in manufacturing:

PROS	CONS
Virtual testing analysis	Expensive and time consuming
Increased efficiency	Requires skilled personnel with knowledge in AI, IoT, data analytics, and system modelling.
Cost reduction	Data quality issues
Improved product quality	Cybersecurity risks
Better decision making	Low-latency networks to ensure real-time data syncing with physical systems.
Adopting cut-edge technology	Lack of stable, sustainable, and collaborative technologies hinders full-scale deployment.

Table 1: benefits and disadvantages of DT

FACTORS	SUB FACTORS
IoT, IoS, and related technologies	Data exchange, connectivity and networks
CPS and CPPS	Integration of computational algorithm and virtual objecting
Big data and analytics	Cloud computing and visualization
Cyber security	End user security, operational security, network security and information security
System integration	Horizontal integration and end to end integration
Other techniques and tools of integration	Augmented reality simulation and standardization of manufacturing components using twin technology

QMS Virtual Modelling and Simulation of Manufacturing Processes for Industry 4.0.

Industry 4.0 alludes to the digital transformation of industry that results from full connectivity and automating of all production processes. Sensors on equipment, machinery, substances, and end products detect environmental variables and processing status and interact with one another via software that is embedded. Industry 4.0 is based on ideas and innovations that include: Internet of Things (IoT), Internet of Services (IoS), and Cyber-Physical Systems (CPS).The system is based on Internet contact, allowing for continuous collaboration and information exchange among humans, machines, and both.

Industry 4.0 enables cost-effective, high-quality customization with faster processing. The idea is to have resources, machinery, and smart goods all work together in an autonomous fashion to maximize efficiency in real time. With this idea, businesses may streamline their manufacturing processes and make individualized goods for the same price as mass-produced ones.[8].

Critical elements of industry 4.0

Industry 4.0 focuses on manufacturing automation and includes technologies like CPS, IoT, and cloud-based computing. Industry 4.0 is a popular research topic in both industry and academia. Industry 4.0 is being tested in various fields, including health care, smart cities, electricity systems, child-care services, supply and distribution systems, fire dealing with, autonomous vehicles, communication, and transportation[8].

Table 2: elements of virtual simulation of manufacturing process industry 4.0

Digital twin Transformation to Improve Quality Management Systems

- ✓ Enhancing data integrity and traceability

  Data integrity is an important part of Quality Management Systems in pharmaceutical companies. This term relates to the accuracy, completeness, uniformity and dependability of data throughout its lifecycle, including generation, processing, and storage. Digital transformation provides a powerful answer to these difficulties by automating data acquisition, validation, and analysis[9].
- ✓ Improving process oversight and monitoring.

  A pharmaceutical quality control procedures must include process oversight and control to guarantee that manufacturing procedures continuously yield goods with the necessary quality standards. Digital transformation improves process management and monitoring through real-time data collection, investigation, and visualization.

  IoT and smart sensors can constantly track critical process parameters like humidity, pressure, temperature, and pH in manufacturing. Digital twin technology can provide a virtual version of a manufacturing process, allowing for real-time simulation and improvement of process parameters. Digital twins use historical process data and predictive algorithms to discover optimal operating parameters for each stage, minimizing unpredictability and improving product quality[10].
- ✓ Offering decision-making and quality analysis in real-time

  Effective pharmaceutical quality management requires ongoing improvement through quality analytics and decision-making. Digital transformation allows for real-time quality analytics and decision-making through sophisticated analytics, AI, and machine learning technologies. AI-powered decision support systems can help quality managers make fast and informed decisions, including CAPAs, process optimization, and quality improvement efforts[10].
- ✓ Streamline document oversight and instruction

  Using electronic document management systems (EDMS) and digital collaboration tools can improve document management and training by centralizing quality-related records, allowing for version control, secure access, and electronic signatures. This ensures that all people have possession of the most current papers and can simply search and share content across the firm[11].
- ✓ Facilitating continual enhancement and invention.

  A pharmaceutical quality management system requires continuous development and innovation to optimize operations and satisfy changing regulatory standards and patient needs. Digital transformation enables constant enhancement and creativity by offering tools, data, and insights for identifying optimization possibilities and developing new solutions. Computational fluid dynamics (CFD) and finite element analysis (FEA) allow for virtual design and testing of new goods, processes, and equipment, saving time and money compared to actual experimentation. Digital transformation may strengthen pharmaceutical quality management systems by increasing data integrity, traceability, and allowing real-time quality monitoring and decision-making[12].

Limitations of Implementing a Digitally Assisted Quality Management System

- ❖ Legacy systems and equipment.

Among the main issues that pharmaceutical companies experience in the context of digital transformation, there is the problem of a lack of understanding of a new way of thinking Existence of legacy systems and infrastructure makes it such that investigations to bolster their Quality Management Systems should be conducted Most of the pharmaceutical companies have lived in decades and their IT systems have changed and now there is a network of various systems, platforms and databases. Being quite ancient, these legacy systems in most cases do not have the ability to serve contemporary data management tools, like real-time data capture, automation of data verification and secure data sharing. Pharmaceutical businesses must evaluate their current infrastructure, identify gaps and constraints, and create a modernization strategy. This process frequently includes transferring data from outdated systems to new devices, integrating multiple systems and the form of databases, and adopting new data governance procedures and standards. Legacy systems may not meet modern regulatory standards for data integrity, including FDA 21 CFR Part 11 standards for electronic records and signatures (U.S. Food and Drug Administration, 2003). Bringing these technologies into compliance may need substantial validation, testing, and documentation, increasing the level of difficulty and cost of digital restructuring programs[13].

- ❖ The accuracy of data and consistency issues

Data quality and standards concerns provide a substantial hurdle to implementing a digital Quality Management System. Pharmaceutical companies frequently use multiple databases and software programs for various functions, including research and development, Production, surveillance of quality, and regulatory affairs. Integrating and transferring data between these systems can be challenging due to differences in data formats, vocabulary, and standards. Incomplete, incorrect, or inconsistent data can result in poor decision-making, higher risk of non-compliance, and significant patient safety concerns. To improve data quality and consistency, pharmaceutical businesses should use standardized data forms, ranging vocabularies, and interfaces. The Allotrope Foundation's Allotrope structure along with the OPC Unified Architecture (OPC UA) standard offer a single language and structure for data exchange across systems and organizations[13].

- Cybersecurity threats and data privacy problems

Pharmaceutical businesses are increasingly relying on digital technology to handle and trade data, raising cybersecurity and privacy issues. Cybercriminals may target pharmaceuticals organizations to steal confidential data, such as trade secrets, patient data, or accounting information, or to disrupt operations with ransomware or denial-of-service attacks. Data breaches may cost pharmaceutical businesses financially, ruin their brand, and result in regulatory fines.Pharmaceutical businesses should install strong security measures, including firewalls, encryption, access restrictions, and intrusion detection systems, to reduce cyber security risks and preserve data privacy. Companies should undertake frequent security evaluations, scans for vulnerabilities, and penetration testing to discover and remediate system and network flaws. Companies should offer regular cybersecurity education and awareness initiatives for employees to foster an attitude of security and vigilance[14].

- Authentication and compliance for digital systems

In the pharmaceutical sector, computerized system validation and compliance are crucial for maintaining data integrity and quality management effectiveness. Validation is the process of documenting a computer system's intended performance, whereas compliance involves satisfying regulatory standards regarding electronic records and signatures, which include the FDA's 21 CFR Part 1. Validating and ensuring compliance with computerized systems may be tough, especially during digital transformation activities involving novel innovations, platforms, and interfaces.Pharmaceutical businesses must adhere to industry standards and regulations, including GMP and ISO 9001, while designing, developing, and maintaining computerized systems. Companies must create and implement validation strategies, test methods, and risk assessments, and keep detailed documentation of validation and compliance operations. Companies must regularly monitor and manage computerized systems throughout their lifespan, including validation and compliance initiatives. Automated evaluation and verification technologies can help companies save time and effort on manual testing and reporting. Companies can leverage the knowledge and best practices of technology vendors and providers of services who have validated and qualified computerized systems in pharmaceutical companies.Implementing a digital quality administration Standard in the pharmaceutical sector is not without hurdles. Pharmaceutical companies face challenges in achieving digital transformation, including outdated systems and facilities, accuracy of data and standardization difficulties, resistance to change, cybersecurity risks, and computerized system validation and compliance. Pharmaceutical businesses may successfully utilize digital technology to improve their system for quality management by taking a strategic, risk-based, collaborative approach and utilizing the latest research and industry standards[14].

Strategies for Effective Digital Evolution of Quality Management Standards

- Establish an extensive digital transformation blueprint.

Establishing a digital transformation strategy requires cross-functional cooperation and input from stakeholders such as executives, IT, assurance of quality, laws and regulations, and operations. Engaging varied viewpoints and skills may guarantee pharmaceutical businesses' digital transformation programs are comprehensive, cohesive, and sensitive to the demands of various departments and users. The digital transformation plan should be fluid and responsive to changes in business goals, technology, and regulations. Pharmaceutical businesses may use a quick and iterative strategy to reduce risks, learn from mistakes, and leverage on new possibilities[15].

- Investing in contemporary, scalable, and compliance IT infrastructure.

Pharmaceutical companies must make investments in contemporary, adaptable, and in accordance IT infrastructure to support integrating data, analysis, and exchange across systems and functions, ensuring effective digital transformation and regulatory compliance. This framework should be developed to prioritize interoperability, adaptability, and conformance to industry laws and standards. Cloud computing technologies, including IaaS, PaaS, and SaaS, provide pharmaceutical firms cost-effective and secure alternatives for storing and processing information and application deployment. Pharmaceutical businesses ought to spend in advanced security technology, including intrusion detectors, firewalls, encryption, and access restrictions, to safeguard against cyber threats and illegal access[15].

- Implementing data management and integrity programs.

Data governance and reliability are crucial for digitization and regulatory compliance in the pharmaceutical business. Data governance alludes to the procedures, policies, and structures that regulate how data is collected, stored, processed, and utilized inside an organization. Data integrity ensures correctness, completeness, consistency, and dependability throughout its lifespan.Specific roles and duties for data management, ownership, and quality assurance are essential for pharmaceutical businesses to develop successful data administration and integrity programs. This involves developing data guidelines, metadata, and taxonomies, as well as putting in place data validation, conciliation, and verification methods to assure data correctness, consistency, and traceability. Pharmaceutical firms should prioritize risk-based governance of information and integrity, concentrating on important aspects and procedures that affect product quality, safety for patients and regulatory compliance. Regular risk assessments, evaluations of gaps, and records quality audits help firms highlight areas for improvement, manage resources effectively, and maintain regulatory compliance[16].

- Developing a community of quality and constant development.

Successful digital transformation in the pharmaceutical business requires fostering a culture of quality and continual improvement. This entails building an atmosphere in which workers at all levels recognize the value of quality, have the authority to report problems and offer changes, and are encouraged to adopt new technology and work techniques.Pharmaceutical organizations should foster an atmosphere of transparency, cooperation, and information sharing, allowing employees to address issues, share lessons learned. Creating platforms for cross-functional conversation, such as community of practice or creativity labs, may encourage collaborative ownership and accountability for quality, driving the implementation of digital transformation beyond the company's hierarchy[16].

Case Studies and Industrial Relevance

The pharmaceutical industry is using digital twins to improve operational continuity, reduce risks, and speed quality-driven manufacturing. The following are noteworthy instances of how industry leaders use digital twin technology.

- Pfizer: Artificial Twins for Vaccine Manufacturing.

Through the COVID-19 pandemic, Pfizer and BioNTech used digital twin models to speed vaccine manufacture to satisfy extraordinary worldwide demand. The digital copies were used to replicate end-to-end manufacturing, including.

Bioreactor dynamics: forecasting cell culture behaviours. Real-time monitoring of materials inventory and equipment performance.

AI-enhanced twin models estimate quality outcomes using previous process data.

Impact: Pfizer reported a 20-25% reduction in time-to-batch release and dramatically decreased process variances through proactive anomaly identification. This also facilitated immediate regulatory alignment, which sped up the Emergency Use Permission procedure.

- GSK: Facility-wide Twin Platforms for Batch Consistency.

GlaxoSmithKline (GSK) used facility-scale digital twin technologies in many biologics production plants. The goal was to achieve batch-to-batch uniformity, particularly in extremely sensitive antigen-antibody (mAb) manufacturing.
Digital twins collected data from cleanrooms, HVAC systems, and equipment-level PLCs.
group genealogy models were utilized to trace inconsistencies down to their source causes.
Integrates alongside MES and LIMS software to provide complete data lifecycle insight.
Impact: GSK increased batch output by 15% and reduced failures by 30% with predictive warnings and improved maintenance cycle scheduling.

- Novartis: Prospective Quality Assurance by employing Digital Replicas.

Novartis integrated digital twins into their Industry 4.0 plan, including continuous production and QA/QC procedures. These computerized copies not only imitate equipment behaviour, but also quality assurance procedures.
Parameter mapping in real time between laboratory and production settings.
ML-driven digital twins helped with predicted release testing, reducing the need for human lab labour.
Used for cross-plant uniformity in global production sites.
Impact: Novartis experienced a forty percent decline in QA intervals and an 18% decrease in downtime owing to early detection of calibration deviations and machine degradation[17].

Future Developments & Prospects

- ❖ Implementation of blockchain-based technologies for supply chain accountability and data consistency

Blockchain technology can improve supply chain openness and data accuracy in pharmaceutical companies. Blockchain technology allows for safe and auditable monitoring of medications from production to delivery, eliminating the danger of counterfeiting and assuring regulatory compliance.Blockchain technology can secure data connected to Quality Management System (QMS), including batch documents, test results, and certifications for examination.Integrating blockchain with IoT and AI can create autonomous quality control systems that identify and respond to issues in real-time. Blockchain technology's implementation in the pharmaceutical business is expected to increase the security of data, traceability, and regulatory compliance [18].

- ❖ Integrating internet of things devices for actual time quality tracking and predictive maintenance.

The Internet of Things (IoT) is a network of gadgets that are connected, sensors, and the actuators that gather and transmit data in real-time. It can be utilized in manufacturing machines, storage spaces, and logistics systems to monitor critical quality parameters like humidity, temperature, and pressure. Pharmaceutical firms may obtain significant insights into their production processes and assets by analyzing data from IoT devices using advanced data analysis and machine learning algorithms. Predictive maintenance detects and addresses prospective equipment breakdowns or quality concerns ahead of time, minimizing interruptions waste, and compliance risks.Pharmaceutical firms may use IoT data and artificial intelligence-powered systems for decision support to improve quality, decrease mistakes, and assure regulatory compliance[18].

- ❖ Utilizing deep learning and big data analytics for continual quality improvement.

Big data and machine learning techniques are revolutionizing pharmaceutical businesses' quality management and ongoing improvement strategies. Using organized and unstructured data from multiple sources, including production processes, quality assurance tests, and feedback from customers, firms may acquire insights into issues affecting product quality and performance.Machine learning algorithms may find trends, correlations, and anomalies in historical quality data, indicating possible faults or chances for development. These systems may monitor high-quality information in actual time, alerting to abnormalities and allowing for proactive remedial steps. Big data machine learning and analytics can help adopt advanced quality procedures, like MSPC and PAT. Combining process, quality, and product data allows for real-time condition evaluating, prediction, and optimization, leading to reduced variability and improved process capacity[19].

- ❖ Collaborate with authorities to create nationwide regulations regarding digital quality management.

Effective digital improvement of management systems for quality in the pharmaceutical business involves collaboration among firms, regulators, and industry groups. As digital technologies disrupt traditional quality oversight approaches, there is a need for industry-wide regulations and standards to provide consistent, reliable, and secure digital quality data and procedures. Regulatory agencies, including the FDA and EMA, have issued rules and regulations on the adoption of technology in the pharmaceutical industry, covering integrity of data, computerized system validation, and electronic records. However, there are no consistent standards or best practices for integrating digital technology into quality management.Collaboration among pharmaceutical firms, technology providers, and regulators may bridge the gap and establish industry-wide standards for digitized quality management. Participating in manufacturing consortia like ISPE and PDA can help companies create guidelines, templates, and tools for implementing technological innovations in compliance with regulations. Digital technologies like blockchain, IoT, big data analysis, and artificial intelligence are transforming the pharmaceutical industry's quality management systems.These technologies may increase supply chain transparency, monitor quality in real-time, forecast maintenance, and drive continuous improvement. To guarantee consistent, reliable, and secure digital quality management, coordination among pharmaceutical firms, regulators, and industry groups is crucial for effective implementation. By embracing future trends and possibilities, the pharmaceutical sector may improve quality, efficiency, and patient-centricity while meeting regulatory obligations[20].

CONSLUSION

The use of digital twin technology in drug production and quality management systems is a big step toward Pharma 4.0. Digital twins improve operational efficiency, maintenance planning, and making decisions by developing dynamic, real-time virtual models of production processes. This leads to better product quality and better patient outcomes. These innovations not only help with problems that have been around for a long time, including data integrity, process surveillance, and compliance, but they also make new solutions possible, like blockchain-enabled transparency in supply chains, IoT-driven analytics for prediction, and AI-powered quality control. Digital twins have real-world benefits, as shown by testimonials from industry leaders like Pfizer, GSK, and Novartis. These benefits include less downtime, faster batch release, better traceability, and better alignment with regulations. But the change won't be easy. Old systems, problems with data consistency, concerns to cybersecurity threats.Strict compliance standards are still major obstacles that need careful planning and strong governance mechanisms. To get past these problems, we need to make smart investments in scalable IT infrastructure, consistent data management procedures, and strong cybersecurity protocols. We also need to create a culture of continuous development and cross-functional collaboration.
Stepping forward, sophisticated technologies such as deep learning, blockchain technology, and large-scale data analysis will help the pharmaceutical industry maintain security, reliability, and efficiency. Collaboration among regulatory agencies, technology providers, and drug companies will be essential for developing industry-wide standards and guidelines. Finally, by adopting the digital revolution, the pharmaceutical business can accomplish not just increased efficiency and compliance, along with a more patient-Centered approach, providing prompt access to safe, efficient, and high-quality medications throughout the globe.

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