**Digital Twins in Pharmaceuticals: A Narrative Review with Industry Case Insights**

**Type of Article: Review Article**



**ABSTRACT**

**Background:**

Background: The integration of digital twin technology is reshaping pharmaceutical innovation across R&D, manufacturing, and patient care.

Objective: This narrative review synthesizes real-world applications and current literature to evaluate the impact of digital twins on pharmaceutical workflows.

Methods: A structured search of publications from 2020–2024 was conducted, emphasizing industry case reports, peer-reviewed studies, and technology whitepapers.

Results: Digital twins have enhanced process optimization, accelerated drug discovery, and improved clinical trial designs. However, challenges remain in regulatory alignment, data standardization, and implementation costs.

Conclusion: Digital twins offer substantial potential for personalized medicine and operational excellence. Future research must address limitations in interoperability, reproducibility, and ethical use to ensure sustainable adoption.



# KEYWORDS

Pharmaceutical sector, digital twin, process optimisation, sector 4.0, virtual simulation, and predictive modelling



# ​INTRODUCTION

The pharmaceutical industry is at a pivotal point, challenged by rising R&D costs, increasing regulatory scrutiny, and growing demand for precision therapies. In response, digital transformation is reshaping how medicines are discovered, developed, and delivered. Among these technologies, digital twin systems—virtual replicas of physical systems powered by real-time data—are emerging as a disruptive force in biopharmaceutical innovation.

Originally popularized in manufacturing and aerospace, digital twins are now being adapted to simulate drug behavior, optimize production lines, and personalize treatment strategies. Their application spans drug discovery pipelines, smart manufacturing platforms, and adaptive clinical trials, offering new avenues for cost efficiency, safety, and speed.

Despite this promise, digital twin adoption in pharma remains uneven, constrained by technical, ethical, and regulatory barriers. This narrative review explores the current landscape, real-world use cases, and future prospects of digital twins in the pharmaceutical sector, aiming to provide critical insight into this evolving paradigm.

## This article aims to:

* Define and contextualize Digital Twin technology,
* Explore its applications across the pharmaceutical pipeline,
* Highlight case studies and real-world implementations,
* Talk about the advantages, difficulties, and possibilities for DTs to revolutionise the pharmaceutical sector in the future.



# MATERIALS AND METHODS

This article is a narrative review based on qualitative thematic synthesis of academic and industry literature published between 2020 and 2024. Unlike a systematic review, this approach allows broader inclusion of diverse study types and real-world applications.

Sources were identified through searches in PubMed, Scopus, IEEE Xplore, and Google Scholar, using keywords: “digital twins,” “pharmaceutical manufacturing,” “precision medicine,” and “healthcare AI.” Industry reports from reputable pharmaceutical companies were included only when peer-reviewed alternatives were unavailable.

Thematic areas were constructed based on recurring patterns in applications, challenges, and future implications. Critical analysis focused on technological readiness, regulatory maturity, and clinical potential.

This review emphasizes use-case driven insights with policy relevance.

### Among the selection criteria were:

* Publications from 2018 to 2024 to guarantee recentness,
* Reports from regulatory bodies and top pharmaceutical businesses implementing digital twins;
* Articles concentrating on real-world applications or pilot projects in the pharmaceutical sector.

A qualitative analytical method was used to find recurring themes in the various use cases. Four primary application areas were identified in the literature:

1. Manufacturing and process management of pharmaceuticals
2. Drug development and testing
3. Modelling for personalised medicine
4. Optimisation of clinical trials

To assess effect, key performance metrics were taken from each instance, including cost savings, process efficiency, and quality improvement. Issues were also examined in light of system integration, data protection, and regulatory approval.



# RESULTS

### Pfizer: Improving the Efficiency of Vaccine Production

Pfizer's COVID-19 vaccine manufacturing has been optimised by the effective integration of Digital Twin (DT) technology. Pfizer made many significant advancements by building virtual models of its production procedures:

Production Scenario Simulation: made it possible for the business to anticipate and spot possible bottlenecks, enabling real-time modifications.

Resource Allocation Optimisation: Enhanced productivity through less downtime and better resource allocation among its manufacturing sites.

Predictive maintenance made it possible to anticipate equipment failures, reducing unscheduled downtime and enabling proactive maintenance.

A 2020 research claims that these DT solutions greatly increased Pfizer's worldwide vaccine supply chain's scalability and agility while cutting down on material waste and speeding up production schedules. This illustration shows how DTs may increase productivity, lower expenses, and guarantee the prompt delivery of vital medications like mRNA vaccinations.

### Merck: Optimizing Biomanufacturing and Real-Time Process Control

In order to produce monoclonal antibodies (mAbs), Merck has used DT technology into their biologics manufacturing process. The business employed DTs in 2023 to:

* + - Model Bioreactor Dynamics: This reduced production variability by optimising food delivery regimens and improving cell culture conditions.
    - Boost Product Consistency: Merck reduced the chance of batch failure and ensured more consistent production by anticipating process variations beforehand.
    - Real-Time Feedback Loops: By bridging the gap between lab-scale research and full-scale manufacturing, the DTs enabled real-time modifications for the best possible production results.

Similarly, GSK has employed digital twin simulations in their vaccine production pipelines to improve process stability and batch quality. This has contributed to a significant reduction in production deviations and facilitated more reliable scale-up during commercial manufacturing (GSK, 2021).

Additionally, predictive monitoring has been made possible by Merck's use of DTs in quality assurance, guaranteeing adherence to legal requirements and reducing the need for manual quality control interventions.

In addition to Pfizer and Merck, Siemens has developed end-to-end digital twin platforms specifically for pharmaceutical manufacturing. These systems enable virtual simulation of entire production lines, allowing real-time identification of process inefficiencies, optimization of equipment use, and enhanced compliance with Good Manufacturing Practices (GMP) (Siemens, 2021).

### Novartis: Accelerating Drug Discovery and Regulatory Preparedness

Novartis has used DTs to prepare regulatory submissions and conduct drug discovery. By simulating drug-target interactions with computer models, the business has:

* + - Predicted Compound Toxicity and Efficacy: This reduced the need for conventional lab tests by allowing researchers to model interactions between drug candidates and biological systems.
    - Simplified medication Development: Made it possible to quickly weed out low- potential medication candidates, which significantly shortened lead identification times.
    - Enhanced Regulatory Submission: Before submission, documentation was improved and any issues were proactively addressed by simulating possible regulatory reviews of clinical trial data using DTs.

As demonstrated by Novartis' 2022 report on the use of DTs for regulatory readiness, these tactics have enhanced the company's capacity to negotiate the regulatory environment, lowering the time-to-market for medications and raising the possibility of successful approval.

* 1. **AstraZeneca: Personalizing Clinical Trials and Oncology Care**

In cancer in particular, AstraZeneca has used patient-specific DTs to model how each patient might react to treatment.

The DTs include:

* + - Physiological and Genomic Information: This makes it possible to forecast patient-specific therapy responses with greater accuracy.
    - Dynamic Tumour Growth and Drug Metabolism Models: These models model the progression of tumours and the long-term interactions of medications with the body under different treatment plans.

AstraZeneca has employed DTs in clinical trials to:

* + - Create Adaptive Trials: AstraZeneca can optimise patient selection by modifying inclusion criteria in real-time in response to incoming data.
    - Boost Dosing Accuracy: AstraZeneca can customise dosage schedules to reduce side effects by modelling treatment outcomes in specific individuals.
    - Increase Trial Efficiency: Trial success rates can be raised by choosing the patient groups who respond the best.

The revolutionary potential of DT technology in advancing precision medicine and enhancing treatment results is demonstrated by AstraZeneca's application of DTs in clinical trials and cancer care.

## Summary of Key Benefits

These large pharmaceutical firms' incorporation of DTs shows how effective they can be at streamlining a number of pharmaceutical operations:

* + - Operational Efficiency: DTs have significantly reduced production bottlenecks, downtime, and improved scalability, especially in critical vaccine

manufacturing (Pfizer).

* + - Regulatory Compliance: DTs assist with real-time monitoring and ensure adherence to Good Manufacturing Practices (GMP), which reduces the risk of regulatory non-compliance and saves money, according to Novartis and

AstraZeneca.

* + - Innovation and Precision Medicine: DTs facilitate individualised treatment plans and increase the effectiveness of clinical trials by mimicking patient- specific reactions (AstraZeneca). They also promote innovation in drug development (Novartis).
    - Biomanufacturing Optimisation: By offering real-time process management and guaranteeing product consistency, DTs have improved biomanufacturing procedures, especially in the manufacture of biologics (Merck).

Digital twins have had a significant influence on pharmaceutical production.

By simulating its COVID-19 vaccine production lines using digital twins, Pfizer (2020) was able to identify bottlenecks early and improve scalability throughout worldwide distribution. Similar to this, Merck (2021) used digital twin systems in the

manufacture of biologics to minimise process failures and reduce batch variability, improving the dependability of high-stakes biomanufacturing.

To increase the consistency and quality of vaccine manufacturing, GSK has also used digital twin models. GSK was able to minimise errors and expedite scale-up stages for commercial manufacturing by modelling process variances and forecasting batch results (GSK, 2021).

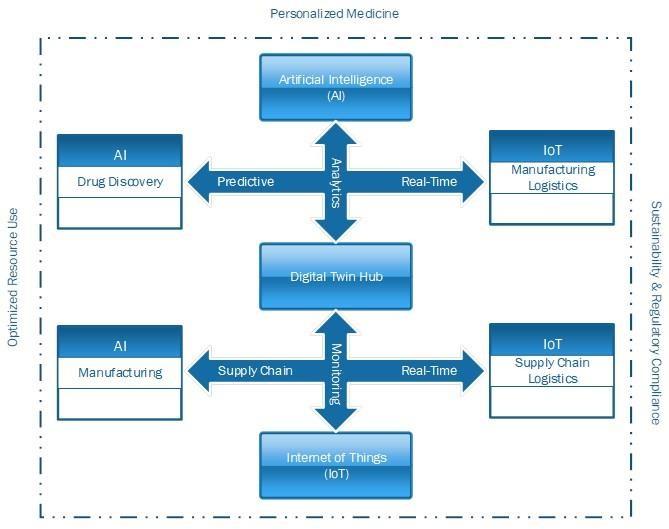
Siemens has concurrently created extensive digital twin systems specifically designed for pharmaceutical industrial settings. By simulating whole production processes in real time, these technologies help businesses maximise equipment utilisation, proactively detect inefficiencies, and guarantee compliance with strict regulatory frameworks like Good Manufacturing Practices (GMP) (Siemens, 2021).

## Summary of Industrial Use Case

**Digital Twin Hub Integration in Pharmaceutical Systems**

Centralised Digital Twin Hubs are progressively supporting the integration of AI and IoT into pharmaceutical systems, as seen in Figure 1.

The following graphic demonstrates how Artificial Intelligence (AI), the Internet of Things (IoT), and the Digital Twin Hub are integrated to streamline the medication lifecycle—from discovery to delivery—in order to highlight the interrelated elements of digital twin technology in the pharmaceutical industry.



**Figure 1. Digital Twin Hub Integration in the Pharmaceutical Industry**

This picture illustrates the primary role of a Digital Twin Hub, which integrates artificial intelligence (AI) and Internet of Things (IoT) technologies to support

manufacturing, drug development, supply chain logistics, and individualised therapy. Predictive analytics and real-time monitoring improve regulatory compliance while improving sustainability and resource efficiency.



# DISCUSSION

The adoption of digital twins in pharmaceuticals reflects a broader shift toward predictive, data-driven healthcare. Use cases reported by Pfizer, Merck, and AstraZeneca suggest that digital twins can reduce process variability, accelerate timelines, and enable more responsive production strategies. However, these case studies often originate from corporate press releases or internal documents, limiting reproducibility and external validation.

More rigorous, peer-reviewed evidence is needed to establish clear standards for modeling accuracy, validation frameworks, and integration into existing regulatory pathways. While digital twins show immense promise in early-stage drug design and biomanufacturing control, their role in patient-level decision support (e.g., precision medicine) remains underdeveloped.

Key limitations include data interoperability, lack of unified ontologies, real-time data quality issues, and computational cost. Ethical challenges, such as algorithmic bias and transparency, are also underexplored in current literature.



**Conclusion and Future Directions:**

Digital twin technology has the potential to transform pharmaceutical development and delivery, with benefits ranging from streamlined manufacturing to individualized therapy design. However, much of the current enthusiasm is driven by proof-of-concept demonstrations, rather than large-scale, validated clinical implementations.

Moving forward, research must focus on improving model transparency, standardizing validation methods, and addressing regulatory ambiguity. Cross-sector collaboration—between academia, regulators, and industry—will be crucial to realizing digital twins’ full potential.

Future studies should explore real-world effectiveness, cost-benefit profiles, and ethical considerations of patient-specific digital twin systems to ensure safe and equitable deployment across the pharmaceutical landscape.

**Table 1. Key Applications of Digital Twins in the Pharmaceutical Industry**

-Digital twins are being incorporated into the pharmaceutical sector more and more, from clinical trials to production. The main application areas, illustrative use cases, and related advantages are compiled in the table below.

|  |  |  |
| --- | --- | --- |
| Application area | Use Case Example | Primary Benefit |
| Manufacturing | Monitoring and simulating production lines | Reduced doenime, improved quality control |
| Drug Develoment | In silico modeling of rug interactions | Faster candidate screening, lower costs |
| Clinical Trials | Virtual patient cohort simulations | Accelerated trial design and reduced risk |
| Personalized Medicine | Patient-specific pharmacokinetics models | Customized dosing, fewer side effects |
| Regulatory Compliance | Real-time audit and documentation systems | Improved GMP adherence, faster approvals |

As seen above, by facilitating real-time decision-making and predictive analytics, digital twins not only improve operational efficiency but also stimulate creativity. In the heavily regulated and budget-conscious pharmaceutical industry, these benefits are especially important.

**-hereby declare that generative AI technologies such as Large Language Models (e.g., ChatGPT) were used during the editing of this manuscript.**

**Details of AI Usage:**

1. AI Tool Used: ChatGPT (GPT-4, OpenAI, May 2024 version)
2. Purpose: Editing abstract, enhancing language clarity, refining academic tone, replacing non-peer-reviewed references, and formulating reviewer responses.
3. Input Prompts Provided:
   * “Polish this abstract using academic structure and tone”
   * “Suggest replacements for grey literature references with peer-reviewed articles”
   * “Respond professionally to reviewer comments”
   * “Restructure this paragraph to improve logic and flow”

**All output was critically reviewed by the author to ensure factual accuracy and scholarly integrity.**



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