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Short communication

Digital Twin Technology: emerging opportunities for pharmaceutical process optimization and risk management

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Introduction

The pharmaceutical industry is rapidly adopting Industry 4.0 technologies, including artificial intelligence (AI), machine learning (ML), Internet of Things (IoT), Process Analytical Technology (PAT), and Digital Twins (DTs) (Yang et al., 2020; Fitzgerald et al., 2025). Regulatory authorities increasingly support science- and risk-based manufacturing approaches to enhance product quality and process robustness. Among these technologies, Digital Twins have emerged as a powerful enabler of pharmaceutical process optimization, predictive control, and quality risk management (Maharjan et al., 2025).

A Digital Twin is a dynamic virtual representation of a physical asset, process, equipment, or manufacturing system continuously updated using real-time operational data. By integrating process models with real-time manufacturing data, DTs enable prediction of process behavior, optimization of operating conditions, and proactive identification of risks before they affect product quality.

Digital Twin Technology in pharmaceutical manufacturing

A pharmaceutical Digital Twin consists of three interconnected elements: the physical system (equipment, production lines, sensors, and utilities), the digital model (mechanistic, data-driven, or hybrid models supported by AI/ML algorithms), and a data management platform that enables real-time data acquisition, analytics, visualization, and cloud-based computing (Yang et al., 2020).

Digital Twins have multiple applications throughout the pharmaceutical product lifecycle. During process development, they facilitate optimization of Critical Process Parameters (CPPs), Critical Material Attributes (CMAs), and Critical Quality Attributes (CQAs), reducing experimental work, development timelines, and costs (Marta et al., 2022). They also support process scale-up by simulating manufacturing conditions before commercial implementation.

In continuous manufacturing environments, DTs provide real-time monitoring and predictive control, allowing manufacturers to identify process disturbances and implement corrective actions before deviations occur (Maharjan et al., 2025). Through simulation and "what-if" analyses, manufacturers can optimize yield, throughput, cycle times, energy consumption, and resource utilization without disrupting production (Marta et al., 2022).

Another important application is predictive maintenance. Through continuous monitoring of equipment parameters such as temperature, vibration, pressure, and flow rates, DTs can detect early signs of equipment degradation and predict potential failures before they occur.

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Digital Twins for quality risk management

Quality Risk Management (QRM) is a core GMP requirement. Digital Twins support all stages of risk management by enabling continuous monitoring, prediction, and evaluation of process performance (Gatkal et al., 2026; Li et al., 2025).

For risk identification, DTs detect abnormal trends that may indicate future failures. During risk assessment, simulations can evaluate the potential impact of deviations on product quality. Risk control is enhanced through predictive interventions that prevent deviations before they occur, while ongoing process monitoring supports risk review and continuous improvement.

Digital Twin technology aligns closely with Quality by Design (QbD) and Quality Risk Management (QRM) principles by supporting design space development, process understanding, control strategy establishment, lifecycle management, and Continued Process Verification (CPV). Virtual simulations allow evaluation of process variability and identification of optimal operating conditions, strengthening process robustness (Yang et al., 2020).

Regulatory perspectives, benefits and implementation challenges

Although specific regulatory guidance for Digital Twin technology is still evolving, its implementation supports the principles outlined in ICH Q8 (Pharmaceutical Development), ICH Q9 (Quality Risk Management), ICH Q10 (Pharmaceutical Quality System), FDA Emerging Technology Program and Continuous Manufacturing initiatives and EU GMP Annexes 11 and 15 (Fitzgerald et al., 2025).

The primary benefits of Digital Twins include improved product quality, increased manufacturing efficiency, enhanced equipment reliability, reduced downtime, faster process development, proactive deviation prevention, and improved regulatory readiness. (Maharjan et al., 2025; Gatkal et al., 2026).

However, implementation challenges remain, including integration of diverse data sources, model validation, cybersecurity concerns, workforce training, and regulatory acceptance of AI-driven decision-making systems.

Conclusion

Digital Twin technology is transforming pharmaceutical manufacturing by integrating real-time process data with advanced virtual models to support process optimization, predictive maintenance, and proactive risk management (Yang et al., 2020; Fitzgerald et al., 2025). As pharmaceutical companies continue their transition toward Pharma 4.0 and smart manufacturing, Digital Twins are expected to become a key component of future digital manufacturing ecosystems, improving product quality, operational efficiency, regulatory compliance, and ultimately patient safety.

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