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Digital Twins: Strategic Guide to Utilize Digital Twins to Improve Operational Efficiency in Industry 4.0

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Abstract: The Fourth Industrial Revolution, known as Industry 4.0, has transformed the manufacturing landscape by integrating advanced digital technologies, fostering automation, interconnectivity, and data-driven decision-making. Among these innovations, Digital Twins (DTs) have emerged as a pivotal tool, enabling real-time monitoring, simulation, and optimization of production processes. This paper provides a comprehensive exploration of DT technology, offering a strategic framework for its effective implementation within Industry 4.0 environments to enhance operational efficiency. The proposed methodology integrates key enabling technologies such as the Internet of Things (IoT), Artificial Intelligence (AI), and Machine Learning to create accurate digital replicas of manufacturing systems. Through a detailed case study, this work demonstrates how DTs can optimize production processes, reduce downtime, and improve maintenance strategies. The findings highlight DTs' transformative potential in achieving continuous improvement, competitiveness, and operational excellence. This research aims to provide organizations with actionable insights and a roadmap to leverage DT technology for sustainable industrial innovation.

Keywords: digital twin; Industry 4.0; operational excellence; Internet of Things; case study

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1. Introduction

The implementation of DTs has proven to be very useful in addressing the modern challenges of Industry 4.0, such as increasing process complexity, the need to reduce downtime, and the goal of improving product quality [1–3]. Recent studies have shown that adopting DTs can significantly improve operational efficiency and reduce costs [4–6].

The scientific literature has shown an increasing focus on implementing DTs in the manufacturing industry. For example, an analysis by Tao et al. in 2017 highlighted how using DTs optimizes manufacturing operations, improves resource management, and reduces waste [2]. The ability to monitor and analyze operations in real-time will enable companies to react quickly to changes in demand and take corrective action before problems become critical [7–9]. In addition, simulating different operating conditions provides a significant competitive advantage, allowing for best practises to be tested and implemented without disrupting day-to-day operations. A further advantage of DTs are their ability to support predictive maintenance [10]. This approach relies on analyzing collected data to predict when faults will occur and take preventive action. This reduces unplanned downtime and improves machine reliability, helping to maintain high productivity. For example, a study by Wang et al. in 2021 showed that implementing predictive maintenance strategies based on DTs can reduce downtime by 20–30% [3]. Furthermore, integrating AI and Machine Learning with DTs can improve product quality. By analyzing the data collected from the sensors, patterns and anomalies that indicate potential quality problems can be identified, enabling timely action to correct them. Zhou et al. demonstrated in his work that AI used for quality management can reduce product defects by up to 15%, significantly improving customer satisfaction and reducing rework costs [11].

The main objective of this paper is to describe a rigorous method for effectively implementing Digital Twins to improve operational efficiency in the manufacturing industry. The proposed method integrates advanced technologies such as the Internet of Things (IoT), Artificial Intelligence (AI), and Machine Learning to develop an accurate digital replication of manufacturing processes. This innovative approach allows for real-time monitoring, simulating, and optimizing industrial operations, providing a detailed and up-to-date view of performance and potential improvements.

The proposed method involves the following steps:

1. Data collection and analysis;
2. Digital model creation;
3. Data implementation;
4. Results verification and validation;
5. Analysis of inefficiency causes.

The developed methodology aims to offer a faithful Digital Twin from which numerous benefits can be derived:

- Improvement of operational efficiency: Optimization of production processes leads to increased productivity and reduced operating costs.
- Reduced downtime: Adopting predictive and preventive maintenance strategies reduces unplanned downtime, improving machine availability.
- Increased product quality: Advanced quality control and data analysis reduce defects and rework, improving overall product quality.
- Decision support: DTs provide data-based decision support, facilitating the implementation of targeted and timely corrective actions.

This paper's final section will then address the implications, limitations, and prospective future developments of the methodology above.

2. Materials and Methods

As previously described, Digital Twins (DTs) virtually represent a product, process, or service. This technology allows for operations to be simulated, predicted, and optimized using real-time data, making it a pivotal element within Industry 4.0 [12–14]. The integration of Digital Twins with technologies such as IoT and Big Data has shown significant improvements in product lifecycle management, reductions in downtime, and enhancements in predictive maintenance strategies [15,16].

Comparing the current use of Digital Twins across various industries highlights both their potential and the existing gaps in their applications. In manufacturing, companies such as General Electric and Siemens have pioneered Digital Twins for real-time monitoring and predictive maintenance, achieving substantial cost savings and efficiency improvements [17,18]. However, while these implementations have demonstrated tangible benefits, the literature often points to a lack of standardized methodologies for DT deployment, which could hinder their broader adoption [19]. Studies emphasize the challenges of creating accurate models, ensuring real-time data integration and managing the complexities of IT infrastructure required for effective DT functioning [20,21].

In the aerospace sector, early adopters like NASA and the US Air Force have leveraged Digital Twins to improve the safety and reliability of flight operations, using DTs to simulate and predict the behaviour of critical systems [10,16]. In recent years, advancements in

Digital Twin technologies have significantly expanded their application potential across various industrial sectors. For instance, the integration of Digital Twins with Artificial Intelligence (AI) has been extensively studied to enhance predictive maintenance strategies, highlighting how AI-guided Digital Twins address challenges such as data inefficiency and model explainability, paving the way for more robust real-time decision-making systems [22]. The pharmaceutical industry, in particular, has the potential to achieve significant results by leveraging these technologies to ensure compliance with strict quality standards while optimizing production. For instance, a study in 2024 explored the transformative potential of Digital Twins in bio-pharmaceutical manufacturing, emphasizing their ability to simulate and optimize production processes, ensure consistent product quality, and predict maintenance needs [23]. These capabilities significantly improve operational efficiency and reduce time-to-market, which is critical in the highly regulated pharmaceutical sector. Another study proposed a requirement-based roadmap for standardizing predictive maintenance automation using Digital Twin technologies [24]. This is particularly relevant for pharmaceutical facilities which often operate under strict regulatory constraints, requiring advanced tools to monitor, predict, and mitigate operational risks. In environments with existing production infrastructure, such as pharmaceutical facilities, methodological advancements in Digital Twin creation are paramount. A recent article presented a com-prehensive approach to developing and validating Digital Twins, particularly in brownfield production environments [25]. The methodology demonstrated quantitative benefits in process optimization and resource efficiency, which are critical in the tightly controlled pharmaceutical sector. Furthermore, the role of service-oriented Digital Twins in empowering smart factories has recently been emphasized. The research underlines the importance of ubiquitous knowledge in improving enterprise performance and fostering human–machine collaboration within modern industrial ecosystems [26]. Although these examples underline the transformative potential of Digital Twins, many implementations remain limited in scope, often focusing on specific assets or isolated systems rather than achieving a fully integrated system-wide approach [27,28].

The literature reveals that while Digital Twin technology is recognized for its potential to revolutionize industrial operations, its application often lacks a comprehensive, systematic approach that integrates the entire lifecycle of production processes. This is particularly evident in sectors like manufacturing, where most studies focus on DT's capabilities in predictive maintenance and isolated optimizations rather than holistic process integration [13]. Additionally, the existing body of research underscores the importance of continuous validation and updating of DT models to maintain their accuracy and relevance, a challenge that remains largely unaddressed in many practical applications [3].

The methodology proposed in this article aims to fill these gaps by providing a rigorous framework for implementing Digital Twins, specifically designed to ensure alignment between the digital and physical systems. Unlike other approaches, which often focus on specific use cases, this framework emphasizes a systematic method encompassing data collection, model creation, and real-time feedback loops, ultimately allowing for continuous process improvement [29].

By integrating these elements, the proposed approach addresses the current limitations identified in the literature and offers a scalable solution that can be adapted across different industries. This underscores the importance of adopting a structured methodology for Digital Twin implementation, as it maximizes the potential benefits of DT technology and supports companies in achieving higher operational efficiency and competitiveness within Industry 4.0.

Table 1 summarizes the key contributions from the existing literature, focusing on integrating Digital Twin (DT) technology across various domains. This table highlights the methodologies, core findings, and application areas explored by different authors.

Table 1. Main contribution considered.

Authors	Year	Title	Main Contribution
Tao et al. [2]	2019	Digital Twin Shop-Floor: A New Shop-Floor Paradigm Towards Smart Manufacturing	Explores DT integration with IoT and Big Data to optimize the product lifecycle
Wang et al. [3]	2022	A review of the technology standards for enabling digital twin	Framework for predictive maintenance based on DT
Qi & Tao [7]	2018	Digital Twin and Big Data Towards Smart Manufacturing and Industry 4.0: 360 Degree Comparison	Analysis of DT as an enabler in smart manufacturing
Boschert & Rosen [10]	2016	Digital Twin—The Simulation Aspect	Emphasized simulation for testing operational scenarios and risk reduction
Zhou et al. [11]	2021	Design of automatic spray monitoring and tele-operation system based on digital twin technology	Demonstrates defect reduction through AI and analytics integration with DT
Grieves [12]	2019	Digital Twin: Mitigating Unpredictable, Undesirable Emergent Behavior in Complex Systems	Foundational work on DT structure and lifecycle management
Jones et al. [13]	2020	Characterising the Digital Twin: a systematic literature review	A review of DT applications and implementation challenges
Lee et al. [15]	2015	Cyber-Physical Systems and Digital Twin Interaction	Highlights CPS's role in enabling real-time feedback for DT functionality
Rosen et al. [21]	2015	About the Importance of Autonomy and Digital Twin for the Future of Manufacturing	Enhances the autonomy of industrial systems
Ma et al. [23]	2024	The Use of Digital Twins to Support Artificial Intelligence-Guided Predictive Maintenance	The integration of digital twins with Artificial Intelligence is examined for predictive maintenance, addressing challenges such as data inefficiency and explainability
Ma et al. [24]	2023	A Requirement-based Roadmap for Standardized Predictive Maintenance Automation Using Digital Twin Technologies	A requirements-based roadmap is proposed for standardized automation of predictive maintenance using Digital Twin technologies
Braun et al. [25]	2023	Qualitative and Quantitative Evaluation of a Methodology for the Digital Twin Creation of Brownfield Production Systems	Developed and evaluated a methodology for the creation of Digital Twins in existing production systems, emphasizing the benefits in optimization
Longo et al. [26]	2022	Ubiquitous Knowledge Empowers the Smart Factory: The Impacts of a Service-oriented Digital Twin on Enterprises' Performance	Explores the role of service-oriented digital twins in improving business performance and promoting smart factories

3. Methodology

The methodology described is summarized in Figure 1, which provides a concise representation of the main phases and key steps involved in the creation of a Digital Twin.

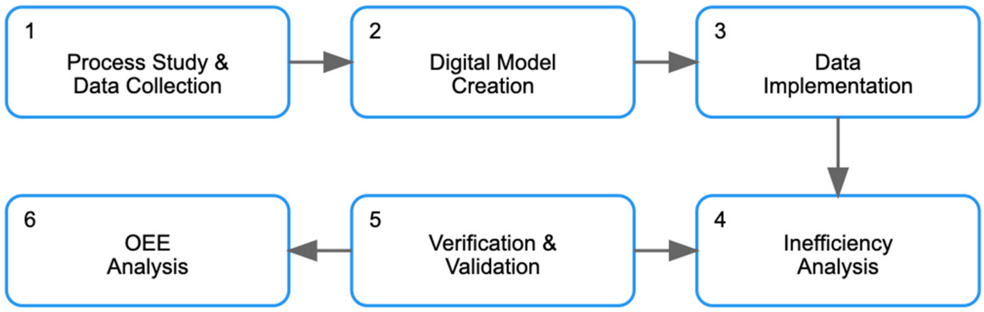

Figure 1. Graphical representation of the method.

The first phase of creating a Digital Twin involves studying the process that needs to be replicated digitally. This process generates a significant amount of data, which can be analyzed to optimize the process and make informed decisions. It is essential to identify the data types required for the Digital Twin, which can come from various sources such as sensors, enterprise databases, and IoT devices. After identifying the data sources, the next step is to determine how to collect the data, which may involve installing new sensors or using existing database systems and IoT technologies. It is also necessary to analyze the production process history to ensure the reliability of the dataset. This analysis should consider periods with no radical changes that would affect the collected data. Once all the preliminary steps are completed, data collection proceeds.

Each production line has a theoretical production capacity, representing the maximum output the system can generate in a unit of time for the given input conditions. This capacity is defined in terms of ideal operating conditions and values, such as the nominal capacity of the machines. However, each production line is subject to several dynamics that inevitably affect performance [25]. Data collection focuses on understanding these dynamics, their causes, and the consequent data determining their line efficiency. These data are crucial because they make each production line unique. It is necessary to focus on these data to create a Digital Twin that can fully describe the production process and learn its behaviour. This phase is therefore the most delicate and time-consuming part of the method. Each step must be approached with the utmost care and attention to ensure the consistency and accuracy of the data, thus providing a solid basis for the subsequent steps. This phase has been identified as the indispensable starting point of the method, as the data collected form the foundation on which the entire Digital Twin development process is based.

The primary indicator required to comprehend the production line and its operational efficiency is overall equipment effectiveness (OEE), which evaluates the overall efficiency. OEE considers three principal factors: machine availability (A), performance efficiency (P), and product quality rate (Q).

The next stage in the production process study is creating the digital model. This model will serve as the virtual representation of the production line, which will be developed through an approach that combines in-depth inspections and detailed measurements.

Initially, a complete examination of the production line must be conducted to fully understand its operations and the degree of interdependence between its components. Next, precise measurements, such as cycle times and production speeds, are taken to acquire quantitative data on the line's performance. These data are then integrated into the digital model to ensure that it reflects the line's behaviour under ideal conditions.

Following this, identifying the bottleneck machine is essential as it dictates the maximum system throughput. This machine has the highest utilization rate and constrains overall production capacity. Real-time data collection and continuous analysis can help ensure that bottleneck identification remains accurate and reflects current conditions. Another critical element is the inclusion of personnel, whose roles and skills must be analyzed to ensure optimal line performance. Unlike robots, which are predictable and easier to model, humans add complexity due to their adaptability and decision-making variability, making the accurate representation of human tasks challenging. To implement personnel effectively, it is advisable to identify the most specific role possible for each operator, considering their skills and capabilities. This will facilitate the implementation process and create optimal conditions for the process to run smoothly.

To create the most accurate digital model, it is important to consider that despite our efforts, it may not be possible to represent everything perfectly due to software limitations or reality complexities. However, the digital model must manage to capture the essential behaviour and functioning of the production process. A model that may not fully reflect the physical specifications but manages better to respect the actual process behaviour and functioning is preferable to a more visually appealing model that is less faithful to reality.

The digital model is then created, considering all the information gathered during inspections and measurements. The model will be able to simulate material flow, machine operation, and all other activities on the production line.

Once all the data characterizing the efficiency and behaviour of the line in the real world have been obtained and a digital model that faithfully reflects the operation of the line under ideal conditions has been created, the next step is the implementation of these data within the model to create a Digital Twin of the process.

In the implementation phase, all factors that may influence the system's operation are considered and calculated in the data analysis phase and are implemented in the digital model. This phase is of paramount importance, as it serves to enable the method.

The data implementation in the digital model follows the guidelines and protocols established by the chosen simulation software. In this case study, Siemens Tecnomatix Plant Simulation X software (2302) was selected for its advanced simulation, optimization, and integration capabilities within Industry 4.0. It enables detailed modelling, scenario analysis, real-time performance monitoring, and predictive maintenance through machine learning. Its seamless integration with IoT and Big Data enhances real-time data collection and analysis. Compared to the alternatives, Tecnomatix surpasses DELMIA in discrete event simulation and cost-effectiveness, ThingWorx in complex simulations and predictive maintenance, and Arena in real-time monitoring and advanced optimization. Despite a steep learning curve and higher initial costs, Tecnomatix's comprehensive features make it the preferred choice for this case study's challenges.

The data implementation process necessitates data transfer into the virtual model, ensuring that all pertinent variables and parameters such as availability due to failures and set-ups are accurately represented. This will enable the software to simulate the failures during machine operations enabling, thanks to simulations, the quantification of the impact of failures on the overall machine availability and operational efficiency and the identification of critical areas in need of improvement. In contrast to the availability due to failures, the implementation of set-up availability is more complex since there is no value, such as MDT, that can be directly used with set-up times. The implementation can be achieved by following the outlined steps:

- Set-up time data collection: To ensure the collection of a sufficiently representative sample of actual operations, these data must be collected continuously and systematically.

- Data preparation: Once the data have been collected, they must be prepared for analysis. This involves the elimination of any anomalies or errors that could distort the results.
- Statistical analysis: To identify the distribution that best represents the set-up time distribution.

Once the most appropriate distribution has been identified and analyzed, the specific parameters (e.g., mean and standard deviation for a standard distribution) are implemented in the machine properties within the digital model, enhancing the software's ability to simulate the set-up times during operations.

Verification and validation of the results are the subsequent steps after the data implementation process within the Digital Twin (DT) development. These steps are needed to ensure that the created digital model accurately represents the real system reflecting the operational dynamics, that the simulation results are reliable and applicable in a real-world context, and to identify and correct any discrepancies between the virtual and real worlds. Without rigorous verification and validation, the Digital Twin risks providing inaccurate results, compromising the operational and strategic decisions based on it.

Verification is the process of confirming that the digital model has been constructed correctly and that it functions as intended. This involves a comprehensive analysis of the simulation code, parameter configurations, and the consistency of the input data. During this phase, various debugging techniques are employed to identify and resolve any errors in the model.

- Model inspection: A manual model check is conducted to ensure that all elements have been implemented correctly and that there are no inconsistencies or logical errors.
- Sensitivity testing: Tests are conducted to check how the model responds to variations in input parameters. This process enables the identification of any instabilities in the model and the confirmation of the consistency of the responses with the expected outcomes.
- Cross-validation: The model's results are compared with historical data to check the consistency and accuracy of the Digital Twin.

Validation ensures that the model meets the requirements for which it was created and that simulation results are accurate to the real system. This process includes various steps:

- Comparison with actual data: The results of the Digital Twin simulations are compared with the actual operating data. This comparison allows for the identification of discrepancies and the calibration of the model to improve its accuracy.
- Performance analysis: A performance analysis is conducted to evaluate the Digital Twin's efficacy in predicting the performance of the real system under various operational scenarios.

  Iterative feedback: The validation process is iterative, whereby the analysis results are employed to implement modifications and enhancements to the model, which is then subjected to further verification and validation.
- To achieve effective verification and validation, several methodologies are employed, each with a specific application and set of benefits:
- Statistical validation: The objective is to ascertain the degree of correlation between the results of a simulation and those of a real-world scenario. Tests such as Chi-Square, Kolmogorov–Smirnov, and Anderson-Darling tests are employed.
- Trend analysis: This is a statistical method used to identify patterns in data over time by comparing trends in simulated data with real data over time. This methodology is useful for verifying that the model correctly captures the temporal dynamics of the real system.

Several studies have underscored the significance of verification and validation in industrial simulation models. For example, an analysis conducted by Lee et al. in 2015 demonstrated that rigorous validation of simulation models is essential to guarantee their applicability in a real-world context [15]. Similarly, a study by Boschert and Rosen in 2016 highlighted the importance of verifying input parameters and simulation results to ensure DT reliability [10].

The growing complexity of industrial systems and the evolution of simulation technologies underscore the increasing necessity for robust methodologies for model verification and validation. This enhances the Digital Twin's reliability and permits the comprehensive potential of simulations to be leveraged for optimizing production processes.

The conclusion of the method entails an analysis of the underlying causes of inefficiency, based on the identification, evaluation, and resolution of factors that impede productivity and increase operating costs. The developed Digital Twin (DT) offers a robust and detailed platform for exploring and resolving inefficiencies within the production system. The Digital Twin (DT) accurately reflects real-world operations and enables production process simulation, analysis, and optimization. The capacity of the Digital Twin (DT) to accurately represent real-world operations and simulate different scenarios also enables an in-depth analysis of operational issues, thereby providing evidence-based decision support. Exploring the potential within the domain of DT enables the identification of current inefficiencies and the anticipation of future problems. Furthermore, it facilitates the continuous optimization of processes. The primary objectives are to enhance operational efficiency, reduce costs, and elevate product quality, establishing a robust foundation for continuous improvement and future innovation. The initial stage of analyzing the causes of inefficiency is to identify the problem areas within the production process. This can be achieved by analyzing data collected in real-time using the DT, which provides a comprehensive overview of the daily operational process. Once the principal causes of inefficiency have been identified, assessing their impacts on the production process is necessary. The Digital Twin enables the simulation of diverse operational scenarios and the assessment of the impact of inefficiencies. Below is the mathematical formalization:

1. System Representation

The Digital Twin (DT) is represented as a dynamic system S composed of the following:

- Physical System (P): The real-world entity being modelled;
- Digital Model (D): A virtual replica of P;
- Data Flow (F): The bidirectional communication between P and D;

The system can be expressed as follows:

$$S = (P, D, F)$$

2. Data Integration

Real-time data from sensors (S) and historical databases (H) feed the DT. The data flow F includes the following:

- Input data (I_t): Current sensor readings at time t;
- Historical data (H_t): Aggregated data up to time t.

$$F = I_t + H_t$$

3. Process Simulation

The DT simulates operational metrics such as Overall Equipment Effectiveness (OEE):

$$OEE = A \cdot P \cdot Q$$

where

- A = Availability (Operational Time/Planned Time);
- P = Performance (Actual Output/Ideal Output);
- Q = Quality (Good Units/Total Units).

4. Predictive Maintenance

Using machine learning models, predictive maintenance identifies potential failures (Fpred):

$$\mathrm{Fpred} = \mathrm{argmax}\ (t \in T)\ P(\mathrm{Ft},\mathrm{Dt},\mathrm{Ht})$$

where P(Ft,Dt,Ht) is the probability of failure at time t given the Digital Twin's current state Dt and historical data Ht.

5. Optimization and Decision Making

The DT optimizes performance by focusing on global objectives such as maximizing Overall Equipment Effectiveness (OEE), throughput, or minimizing total production costs:

$$\mathrm{Max}\ \Phi(x)\ \text{subject to}\ g(x) \le 0$$

where

- x: Decision variables (e.g., machine speed, resource allocation);
- Φ(x): Objective function (e.g., maximize throughput, minimize downtime);
- g(x): Constraints derived from system and cost limitations.

6. Validation and Feedback

The validation process uses statistical methods like chi-square tests to compare simulated data (Dsim) with real-world data (Dreal):

$$\chi^2 = \sum(\mathrm{Dreal} - \mathrm{Dsim})^2/\mathrm{Dsim}$$

Trend analysis ensures the DT reflects accurate temporal patterns by comparing control charts for Dsim and Dreal.

Once the impact of inefficiencies has been evaluated, the subsequent phase is the implementation of the solutions that address them. The Digital Twin permits the testing and validation of solutions in a virtual environment before their implementation in the physical world. This approach mitigates the risks associated with operational changes and optimizes solutions before implementation. Finally, it is essential to continuously monitor the operational process to ascertain whether the inefficiencies have been resolved and the production process is optimized. The Digital Twin facilitates the real-time collection of data and the execution of continuous simulations, enabling the identification of new areas for improvement. This approach to continuous improvement ensures that operational efficiency is maintained and enhanced over time. The application of machine learning and advanced data analysis technologies enables the identification of emerging patterns and the formulation of recommendations for further corrective actions.

4. Case Study

Having provided a general overview of the method, we will now illustrate its practical application within a pharmaceutical plant. The line on which the DT will be developed is dedicated to packaging bottles containing drugs of biological origin, which can be processed in serialized and non-serialized ways. This flexibility is necessary due to the great heterogeneity of customers and destination countries of the drugs produced within the plant.

This section of the paper will be structured following the steps described in the corresponding section of the methodology.

These data were calculated utilizing the company's OEE collection system, obviating the necessity for implementing additional process monitoring systems. This is because the systems already employed were satisfactory for a comprehensive analysis and characterization of the process.

The subsequent phase of the investigation entailed a detailed examination of the process history within the temporal scope delineated by the accessible data. Upon concluding the analysis, it was determined that 2023 would serve as the reference period, given the absence of significant alterations during this time frame.

Once the preliminary operations had been completed, we proceeded with the data collection and analysis by examining the production line. It should be noted that the objective of the data collection was to gain insight into the dynamics, causes, and subsequent analysis of the calculation of the indicators that influence the line efficiency to outline their real production capacity. These data must be fully understood to gain each production line machine's specific and operational characteristics, including the extent of their interconnectivity. During these inspections, the characteristics of each machine were documented, including their operating parameters, nameplate capabilities, and any inherent limitations. However, this document will not include these details to respect the confidentiality of the company and the companies supplying the machinery. Subsequently, the bottleneck machine was successfully identified. The process is reproduced below in Figure 2 under the ASME notation guidelines to guarantee a transparent and intelligible representation of the digital model.

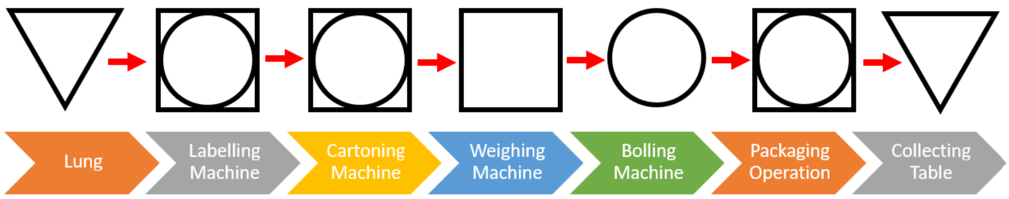

Figure 2. ASME representation process chart.

Finally, the personnel necessary for the production line's optimal functioning and maximum operational performance were appointed. The introduction of personnel was contingent upon a meticulous examination of the roles and competencies indispensable for the productive operation of the line. The resulting digital model, created using the Siemens Tecnomatix Plant Simulation software, is illustrated below in Figure 3.

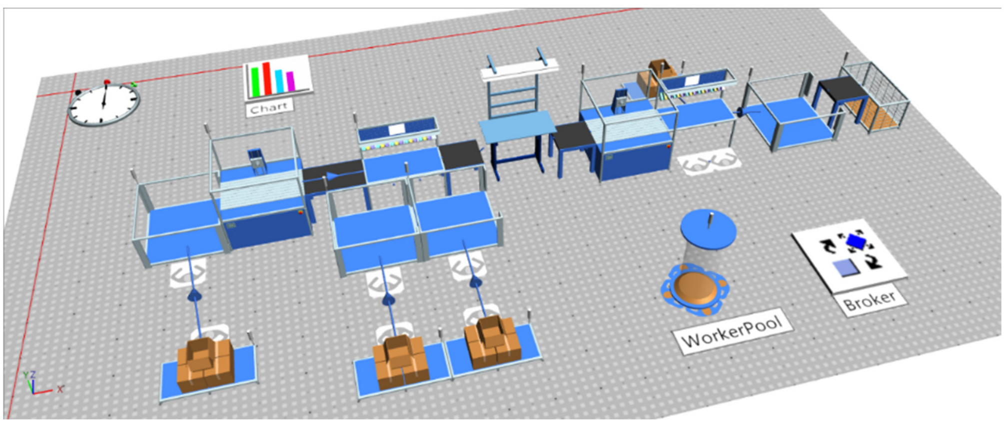

Figure 3. Digital Twin.

The data implementation follows the instructions and protocols established by the software, with particular attention paid to the accuracy and consistency of the data. This process requires the accurate transposition of the real data into the virtual model, ensuring that all relevant variables and parameters are represented correctly and in detail. For the implementation of availability due to failures in the machine properties, and more specifically in the 'Failures' section, it is necessary to activate failures and add the calculated availability due to failures and the Mean Down Time (MDT) of the specific machine. This process must be repeated for each machine using the MDT and Mean Time Between Failures (MTBF) parameters calculated by the system to model the frequency of failures. The software will then be able to simulate failures during machine operations. The next step concerns the implementation of availability due to set-ups within the digital model. In this case, the availability due to set-ups was calculated for the entire line, as the available data do not allow for the availability due to set-ups of individual machines. To begin with, a thorough collection of set-up time data was carried out. These data were collected continuously and systematically to ensure a representative sample of actual operations. Next, the data were cleaned and prepared, eliminating any anomalies or errors that could have distorted analysis results. Following the completion of the data preparation procedures, a statistical analysis was conducted to identify the distribution that best represents the set-up time distribution. After carefully analyzing and comparing opinions with experienced personnel, it was determined that the normal log distribution was the most appropriate for this context. Once the distribution analyses were complete, a further operation was conducted to satisfy the software's request to enter the set-up time distribution per individual machine. The operation involved the parameters calculation of the normal log distribution among the machines according to a proportional logic. This was achieved through observations, in-place data collection, and inquiries from operating and line management personnel. Based on the parameters, a percentage weight was assigned to each machine to reflect the relative complexity, importance, and time requirements of each machine compared to the overall set-up time of the entire line. By multiplying the parameters of the distribution of the entire line by the corresponding attributed weight, the software can accurately simulate set-up times during process operations. Figure 4 illustrates the resource utilization and operational states for various machines in the production system, highlighting the effectiveness of resource allocation and identifying inefficiencies.

The bar chart categorizes machine states into multiple segments, such as Working, Setting up, Blocked, Waiting, and Failed, providing a detailed breakdown of machine activity percentages. The simulations accurately reflected the observed cycle times, set-up times, and failure rates. Moreover, the model exhibited the capacity to adapt to disparate operational scenarios, substantiating its utility as an instrument for optimizing and administering the production process. The data analysis and operational staff feedback confirmed the model's reliability. As illustrated in Figure 3, the cartooning machine has been identified as the main bottleneck in the production line, causing significant inefficiencies. By analyzing utilization data, it was found that the cartooning machine had the highest rates due to delays and lack of synchronization with other equipment. Strategies such as upstream optimization, improved synchronization, predictive maintenance, and capacity expansion were proposed to address these issues. The findings, enabled by Digital Twin, provide a systematic approach to improving productivity.

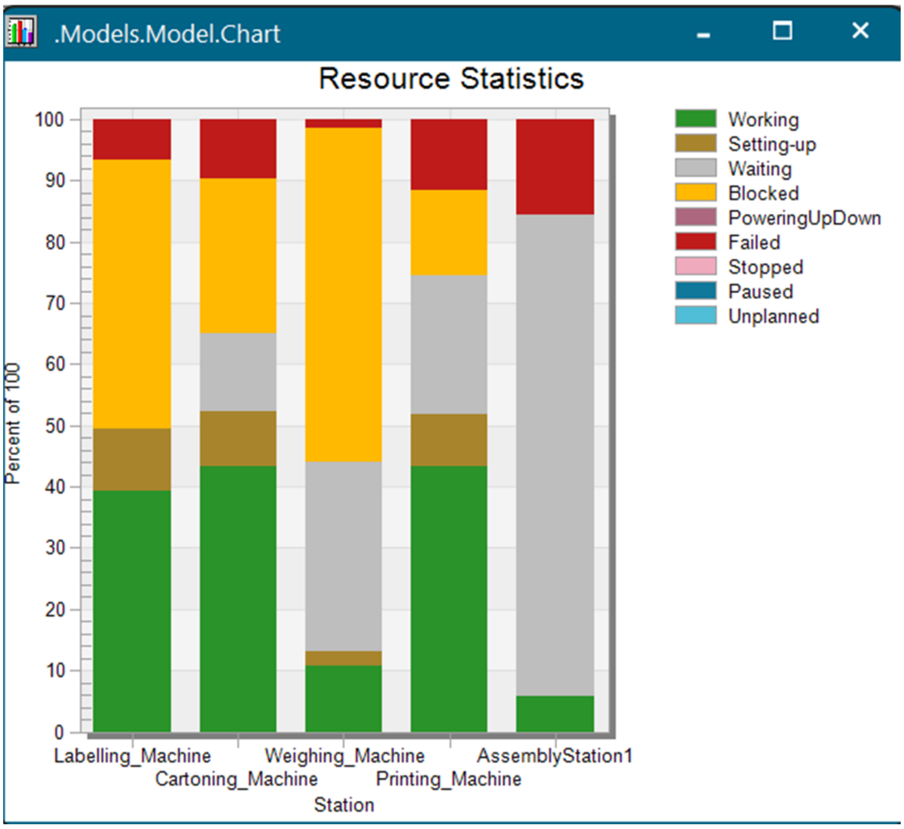

Figure 4. Process machines statistics.

5. Results and Discussion

The proposed method for creating a Digital Twin (DT) was successfully implemented, resulting in an accurate and functional digital model. The process comprised a series of key steps that contributed to creating the Digital Twin using Siemens Tecnomatix Plant Simulation software.

The development of an accurate digital model based on real-time data collected from machines and production processes allowed for a faithful replication of the actual operational dynamics. Data validation using Siemens Tecnomatix Plant Simulation software demonstrated high accuracy, with close to 90% agreement between the digital model and real system performance. This accuracy was further confirmed by analyzing several key indicators, including overall equipment effectiveness (OEE), which showed a strong correlation between the simulated and real values.

This degree of precision enabled the identification of bottlenecks and operational inefficiencies, providing a comprehensive and detailed representation of the production process. One of this analysis's key findings was identifying inefficiencies within the production line. Key areas such as machine downtime and set-up times were highlighted as the main contributors to downtime. Machine uptime, one of the main factors influencing efficiency, was divided into two categories: uptime due to downtime, and uptime due to set-up. The DT highlighted the issue of set-up times, which significantly reduced operational efficiency. Analysis showed that the availability due to set-ups was 70.9%, emphasizing the importance of optimizing these operations. Another identified challenge was frequent machine breakdowns and maintenance delays, resulting in unplanned downtime. Labelling and cartooning machines were particularly affected, with 92% and 91% availability rates, indicating the need for improved preventive maintenance. Breakdowns of the entire production line also impacted line performance, with an availability rate of 88% and a mean downtime (MDT) of nearly 23 min. Overall, the DT highlighted the need for enhanced set-up efficiencies and preventive maintenance to improve the operational performance. Moreover, the operational efficiency of the production line was 77.5%, indicating significant scope for enhancement. The DT's advanced simulation capabilities enabled the identification of the underlying cause of inefficiency, which was attributed to the sub-optimal allocation of resources, including labour and materials. This analysis underscored the potential of utilizing Digital Twin technology to address these challenges by simulating different resource allocations to optimize the operational efficiency of the process. These findings enabled targeted optimization efforts to focus on specific stages of the production process, thereby improving resource allocation and reducing unplanned downtime.

The DT will also provide a robust decision support tool, allowing for managers to simulate different operational scenarios before implementing them on the shop floor. The ability to test various hypotheses, such as increasing production volumes or managing multiple simultaneous breakdowns, provided valuable data for strategic planning. The DT will deliver significant improvements regarding predictive maintenance by providing accurate data on optimal maintenance schedules. The results analysis shows that implementing the Digital Twin can improve overall operational efficiency and be a powerful tool for continuous process optimization. Simulating different operating conditions and test improvement strategies without disrupting live production provides a significant competitive advantage. In addition, statistical validation of the results, including Chi-square tests applied to the OEE metric, confirmed the reliability of the developed Digital Twin. The success of this methodology demonstrates its robustness highlighting its potential to play a central role in future Digital Twin implementations. Its well-structured design and flexibility make it adaptable for effective application across diverse industrial sectors, including pharmaceuticals and beyond. This approach serves as a scalable and versatile framework addressing key operational challenges and aligning with the principles of Industry 4.0. As such, it provides industries with a reliable pathway to enhance productivity, optimize resource utilization, and maintain competitiveness in an increasingly digitalized and interconnected landscape. One of the main implications of the project's success was demonstrating that the DT can serve as a decision support tool for the company. With the ability to integrate real-time data and run detailed simulations, the DT provided valuable information on production line operations, helping managers make more informed and strategic decisions. These simulations allow them to explore a variety of operational strategies and choose the most effective ones to improve production flow by testing their effectiveness without interrupting real operations, reducing risks, optimizing available resources, and reducing costs. This approach has shown how DTs can be used to monitor operations and continuously improve efficiency and productivity. To illustrate, DTs can simulate the impact of different machine configurations, changes in operating parameters, and the introduction of new technologies. This flexibility permits the formulation of well-informed decisions and the implementation of changes with greater confidence, on the basis that solutions have been tested virtually.

Currently, however, the proposed methodology has its limitations, such as the following:

- Information exchange: The exchange of information between the DT and the actual process is manual. This limits the continuity and updating of data, which depend on the frequency and accuracy of manual input operations. Automating this process would make the data update cycle continuous and more efficient, allowing for greater responsiveness and accuracy in operational decisions.
- Implementation complexity: Adopting a DT requires a significant initial investment in time, resources, and technical expertise. Creating and calibrating the digital model requires detailed data collection and close collaboration between engineering and

IT teams. In addition, keeping the DT updated with real process changes can be an ongoing challenge.

- IT dependence: DT performance is closely linked to the IT used, including IoT sensors, communication networks, and data analysis platforms. Any technical problems or disruptions in these systems can negatively affect the effectiveness of the DT, requiring backup solutions and well-defined contingency plans. Dependence on IT also entails continuous upgrades and maintenance investments, ensuring data security and protection against cyber threats.

Future developments in Digital Twin (DT) technology can help overcome its limitations. First, the reliance on manual data exchange processes introduces challenges such as delayed response times, increased risk of errors, and limited scalability. The delays caused by manual data handling compromise the Digital Twin's ability to provide real-time insights and recommendations, which is particularly problematic in applications like predictive maintenance where quick responses are critical. Additionally, the potential for human errors in manual data transfer can distort the accuracy of the Digital Twin and compromise decision-making processes. The manual process also becomes unsustainable in large-scale industrial environments that require a continuous data flow. Automating the data exchange process using automated data collection using real-time analytics sensors and Internet of Things (IoT) devices would make the data update cycle continuous and more efficient, enabling a greater synchronization between the physical system and the Digital Twin and improving its responsiveness and effectiveness in supporting real-time decision-making and adaptive responses. Standardized frameworks for DT implementation would also be beneficial, enabling the integration of different systems and ensuring better data interoperability. The role of human factors in DT systems should be explored, as human operators significantly impact production efficiency. Including human operators in DTs would provide a holistic understanding of the production environment, considering factors such as decision variability, skill level, and fatigue. Integrating human operators and machine automation through human-in-the-loop systems would optimize machine and human performance. In addition, integrating artificial intelligence (AI) with DTs offers opportunities for process optimization. AI algorithms, particularly those using machine learning, can analyze large datasets and make real-time predictive changes, improving decision-making and operational efficiency. AI can also be applied to predictive maintenance, suggesting the incorporation of tailored maintenance programmes based on specific machine conditions. Incorporating AI to simulate human roles within a DT framework can optimize workflows and identify potential bottlenecks caused by human intervention, leading to productivity improvements.

6. Conclusions

This paper highlights the benefits of using a Digital Twin (DT) to enhance a production line's operational efficiency. The DT was developed using Siemens Tecnomatix Plant Simulation software, which accurately replicated the physical production process, enabling the identification of bottlenecks and inefficiencies. The results show a high level of accuracy, confirming the DT's ability to understand and reproduce production line behaviour.

The main impact of the project was the demonstration of the DT as a decision-support tool, integrating real-time data and enabling detailed simulations. This allowed for managers to explore different operational strategies and choose the most effective ones, thereby improving the production flow, reducing risks, and optimizing resources.

This work contributes significantly to the literature on Industry 4.0, providing practical guidance on implementing the DT in real-world scenarios. This detailed case study offers a concrete example of how this technology can improve business operations.

The implementation of the DT in the host facility demonstrated its potential, opening opportunities for other companies to adopt digitization technologies and enhance their efficiency and competitiveness. Integration with emerging technologies like Artificial Intelligence (AI) and the Internet of Things (IoT) could further enhance the analysis and optimization capabilities of the DT, paving the way for industrial innovation. From a managerial perspective, DT integration allows for strategic decision-making by simulating operational scenarios and real-time monitoring, enabling risk reduction, resource optimization, and process improvement. On a broader scale, DT technology contributes to sustainable production practises by optimizing operations, reducing waste, and improving resource efficiency. It also creates a safer working environment by predicting machine failures and reducing unplanned maintenance. In conclusion, this paper emphasizes the strategic role of DTs in Industry 4.0, showcasing their ability to significantly improve operational efficiency and resource management. The success achieved in this practical case provides a solid foundation for expanding DT applications to other industrial contexts, driving the adoption of emerging technologies and enhancing companies' competitiveness. The DT's integration of real-time data, simulations of future scenarios, and optimization capabilities establishes it as a crucial component for the future of modern industry.

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