DIGITAL TRANSFORMATION:
Developing a Fully Automated Pharma Manufacturing Facility

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The move to digital transformation represents a true paradigm shift in manufacturing, enabling organizations to leverage advanced technologies such as the Industrial Internet of Things (IIoT), cloud computing, and artificial intelligence (AI) to ensure compliance and secure a competitive advantage. This article presents a working definition of digital transformation, the components involved in undertaking a transformation initiative, and a phased approach to implementing digital transformation for the pharmaceutical industry.

Digital transformation is helping give pharmaceutical companies the opportunity to develop, manufacture, and deliver life-saving products and treatments to patients more quickly and more sustainably than ever before. Moreover, it does so while improving operational efficiency, cost savings, and flexibility.

The significance of this transformation is underscored by the fact that 90% of all organizations are undergoing some form of digital transformation, whereas the pharmaceutical sector indications are that only 15.1% of survey respondents have not started their digital transformations [1, 2]. For pharmaceutical manufacturers, this shift to digital transformation is particularly critical, because it offers pathways to improved compliance, operational efficiency, and product quality while addressing the need to comply with stringent regulatory requirements.

This article cannot cover or address the depth and breadth of digital transformation for the pharmaceutical industry, but it does layout the high-level steps required for successful implementation. The *ISPE Baseline® Guide: Pharma 4.0™* [3] offers further in-depth guidance, and we recommend discussing this further with a relevant domain expert.

DEFINING DIGITAL TRANSFORMATION

Digital transformation in the pharmaceutical sector involves the strategic integration of operational and information technologies—spanning both manufacturing and business functions—to create a cohesive, data-driven ecosystem. This transformation enables real-time insights that help organizations optimize processes, enhance compliance, and improve product quality. Key principles of digital transformation aligned with business benefits include:

- **Strategic integration:** Aligning each digital initiative with broader organizational goals to ensure coherence and scalability.
- **Data accessibility:** Treating every application, device, and stakeholder as part of a unified information ecosystem to reduce data silos and maximize data utility.
- **Real-time insights**: Using advanced analytics and machine learning to generate actionable intelligence in real time, supporting proactive decision-making.

For pharmaceutical manufacturers, digital transformation also encompasses the development of digital twins and AI-powered drug development. A digital twin can replicate manufacturing processes virtually, allowing pharmaceutical companies to run simulations, predict issues, and ensure product consistency without negatively affecting production. For the pharmaceutical industry as a whole, this transformation is not only about operational efficiency. It is also about the impact on business processes, people and resources, product quality, and patient safety.

There are already some notable successes in life sciences stemming from implementation of digital initiatives. Many pharmaceutical manufacturing companies are members of the World Economic Forum (WEF) Global Lighthouse Network. A recently published WEF white paper indicated the achieved results from two manufacturers' digital transformation initiatives. For one company, their implementations have cut yield variability by 60%, reduced technology transfer time by 50%, and reduced emissions by 31% [4]. Another pharmaceutical manufacturer reportedly upskilled a pool of 3,000 employees. The company

saw a 56% increase in labor productivity while reducing new product development lead times by 67%. More than 50 digital technologies, including machine learning and optimization algorithms, were implemented [4].

The rapid advances in digitization are reflected in recently issued regulatory guidance documents from both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). In early January 2025, the FDA announced the availability for comment of considerations for compliance with 21 CFR 211.110 Guidance for Industry [5]. Key aspects of the document include support for advanced technologies, real-time quality monitoring, process analytical technologies (PAT), and continuous manufacturing systems to streamline operations and improve efficiency.

Two years earlier, in 2023, the EMA published a reflection paper on the use of AI in the medicinal product lifecycle [6]. The reflection paper provides considerations on the use of AI and machine learning (ML) in the life cycle of medicinal products, including medicinal products development, authorization, and post-authorization.

From Industry 3.0 to Industry 4.0 and Beyond

Depending on how one measures it, digital transformation today is actually a journey that began in the 1970s [7]. That historical context is important in understanding where technology is headed for manufacturing in general and the pharmaceutical industry in particular. According to most historians, Industry 3.0 began with partial automation using memory-programmable controls and computers in manufacturing [8].

Although this era brought significant advancements, it also entrenched inefficiencies such as data silos, linear point-to-point integrations, and the accumulation of dark data—information collected through various computer network operations but not utilized for insights or decision-making.

The negative effects of accumulated dark data, when considering the scope, cannot be underestimated. According to an article in *Forbes* in 2021 [9], from information first reported as early as 2016 by the market research firm Forrester [10]—unused organizational data constitutes approximately 73% of all collected data. For the pharmaceutical industry, this data includes information such as environmental monitoring logs, equipment logs, and machine logs, all often stored in inaccessible formats or on standalone equipment systems.

Such limitations curtailed real-time decision-making and hampered operational flexibility. In pharmaceutical manufacturing, data often flows linearly from field devices to control systems and manufacturing execution systems (MES). In many cases, this movement is executed manually, which poses compliance risks under regulatory frameworks such as 21 CFR Part 11 [11] and EU Annex 11 [12]. Manual data handling increases the potential for data integrity violations, including manipulation and falsification, which can compromise regulatory compliance and product quality.

Additionally, the reliance on point-to-point integrations inflated the costs and time required for solution deployment and validation. These challenges are often exacerbated when scaling solutions across multiple sites, particularly at the higher levels of the automation hierarchy where MES and enterprise resource planning (ERP) integrations demand specialized expertise and significant financial investment. The ISA-95 model [13] from years past demonstrates the inefficiency of this approach, with data latency often spanning days or weeks, undermining real-time operational insights.

Industry 4.0, which many academics agree began in 2011 [14], introduced cyberphysical systems and a move toward digital integration of business processes. Industry 4.0 emphasizes real-time data exchange, allowing manufacturers to leverage automation, AI, and ML for operational efficiency. It transforms data into actionable intelligence, fostering agility and resilience in manufacturing operations. Most significantly, it can eliminate many common operational technology and information technology barriers, while maintaining the need for human interactivity and collaborations within that framework.

So what may seem like a relatively recent interest in digital transformation for manufacturing is, in fact, a story more than half a century in the making. Notably, the environmental, societal, and cyber-physical dimensions emphasized in Industry 5.0—such as the circular economy, human-centric design, and resilient supply chains—are already integrated within the ISPE Pharma 4.0 operating model

A PRACTICAL FRAMEWORK FOR DIGITAL TRANSFORMATION

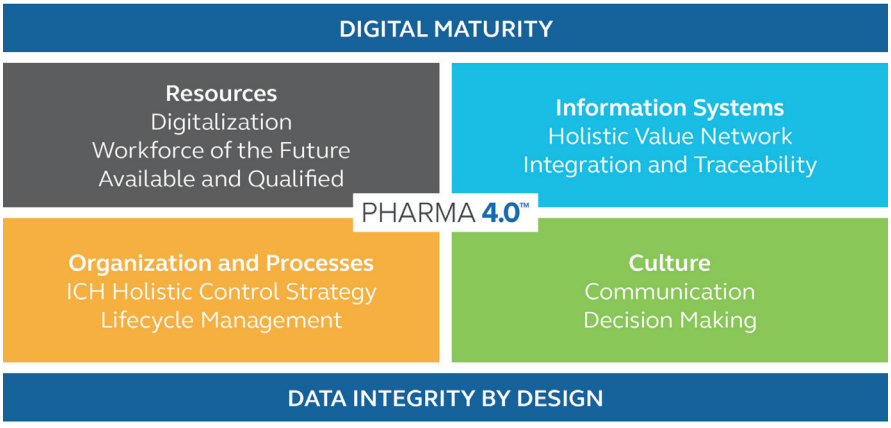
In practical application, digital transformation in manufacturing—and particularly in the pharmaceutical sector—is a journey toward real-time integration of production, people, quality, and business processes, creating an organization that can efficiently consume and act on data. Importantly, digital transformation is not only about adopting new technologies. It is also about changing how companies operate by treating each initiative or project as part of a strategic vision, ensuring data is generated, contextualized, and made accessible without assumptions about its use.

In pharmaceutical manufacturing, digital transformation means connecting automation systems (operational technology, or OT) with IT business processes. This includes :

- **Real-time data utilization:** Leveraging manufacturing and business process data in real or near real time for decision-making
- **Strategic integration:** Ensuring seamless connectivity across equipment, systems, and personnel
- **Data ecosystem:** Treating all nodes (equipment, systems, and personnel) as producers and consumers of data

This integration creates a unified, context-rich information ecosystem capable of driving data-informed decision-making in real time. It enables advanced analytics for informed decision-making, and it ensures compliance with stringent regulatory standards. Before deciding on the relevant solution and applications to solve an organization's particular business and manufacturing challenges, however, it is important to understand the framework applicable

Figure 1: Pharma 4.0 Operating Model



to digital transformation. The digital transformation framework is composed of the following elements:

- Identify business goals and objectives
- Conduct a digital maturity assessment
- Develop a foundation architecture design
- Conduct a pilot project/proof of concept
- Move to full-scale implementation
- Strive for continuous evaluation and improvement

Identify Business Goals and Objectives

It may seem obvious, but unless an organization has consensus on the reasons for adopting digital transformation, results will be scattershot and only marginally successful. Before setting out on the path to transformation, every organization needs a well-articulated digital strategy that defines the importance of digital data for supporting business process decision-making. This well-articulated digital strategy serves as a "north star," providing a clear vision for the organization and aligning efforts across departments. The strategy should define what digital transformation entails for the organization, ensuring that all stakeholders are unified in their understanding and approach.

When developing a digital strategy, organizations must first evaluate and align on their strategic imperatives for digital transformation, and balance those against the risks of inaction. Common objectives include accelerating product development, improving supply chain resilience, and achieving cost efficiencies through process optimization. Failing to adopt digital strategies , despite having such measurable goals, may lead to longer time to market and increased operational costs.

Digital transformation is ultimately an educational journey. Everyone—from shop floor personnel to the C-suite—must share a common understanding of the value of digital data and work to overcome resistance to change. This is also an opportunity to appoint digital transformation champions and form a dedicated team to remove barriers and ensure success.

Organizations can enhance knowledge and training through digital tools such as augmented reality for hands-on learning (e.g., mastering a specific sampling method). These tools should be integrated into the learning management system to ensure compliance, report on training activities, and understand the skills and abilities of all personnel.

Conduct a Digital Maturity Assessment

Conducting a comprehensive digital maturity assessment is essential to understanding whether the organization is ready for digital adoption. This means evaluating technological capabilities, process efficiencies, organizational culture, and leadership alignment. Overall, the key assessment areas include identification of process inefficiencies and pain points, evaluation of cultural readiness for change and potential resistance, and inventory of existing connected systems, data silos, and unconnected devices.

Commonly used and trusted frameworks offer structured methodologies for assessing maturity across many dimensions. These readiness frameworks include the Smart Industry Readiness Index (SIRI) [15], IIoT Digital Transformation Maturity Assessment (DTMA) [16], BioPhorum Digital Plant Maturity Model [17], and ISPE Advancing Pharmaceutical Quality (AQP) maturity assessment tool. For example—and without endorsing any one over the other—the SIRI is an independent digital maturity assessment for manufacturers. It comprises a suite of frameworks and tools to help manufacturers—regardless of size and industry—start, scale, and sustain their manufacturing transformation journeys.

In the pharmaceutical industry, one aspect of digital transformation readiness might include assessing whether batch data from an MES is readily available for real-time analytics, or if manual data review delays decision-making. This assessment would include identifying both good and poor processes and the pain points in the current workflow. The level of cultural readiness could be benchmarked using the AQP St.Gallen Benchmark Questionnaire.

Develop a Foundation Architecture Design

Designing a robust digital architecture is fundamental to ensuring scalable and secure data integration. This includes establishing minimum technical requirements (MTR) that systems must meet to connect to the infrastructure and foster interoperability. This is also the point at which standardized communication protocols may be implemented (such as OPC-UA or MQTT [18]). Many legacy pharma human–machine interface systems actually lack these modern communication protocols and may require gateways to enable standardization.

As in most cases, it is in the foundation architecture design phase that organizational education about digital transformation and digital systems will occur. This education should provide direction to the systems user and future users as to how the transformation will help them in their daily roles and the importance of using data in their day-to-day activities. It enables organizations to plan cultural change management and equipping personnel to adapt to new technologies with confidence.

In this step, the organization may align on a reference Industry 4.0 architecture IIRA [19], RAMI 4.0 [20], SITAM [21], or UNS [22]. For example, an organization may opt for open architecture (not necessarily open technology) that is edge-driven, supports secure data transfer, and complies with global regulatory requirements for data integrity. Importantly, users should not make assumptions about how data is used—if an organization limits the capture of data based on wrong assumptions, it will also limit future insights.

Conduct a Pilot Project/Proof of Concept

You have to walk before you run, and you have to crawl before you walk. It's essential to the success of a digital transformation initiative to not take on more than your organization is prepared to handle at that time. Pilot projects validate the feasibility and effectiveness of proposed solutions. A pilot project or proof of concept is crucial for testing and validation of technology solutions.

To begin, select an area with clear business or manufacturing challenges to validate the solution's effectiveness. In the pharmaceutical context, this could involve a pilot program that integrates equipment data to automatically capture audit logs, alarm records, and event files from process equipment—analyzing the data and feeding relevant information into the electronic batch record. This allows organizations to address tangible challenges while demonstrating value and bringing the organization personnel on-board with the strategy.

For example, a pharmaceutical company implemented a strategy involving system architecture and software integration to successfully pilot a digital transformation in one building within its manufacturing network [23]. The pilot validated that real-time data integration could streamline manufacturing by reducing human intervention and minimizing the risk of data entry errors. Additionally, the project supported the business objective of ongoing process verification (OPV).

Figure 2 illustrates the implemented proof of concept in conceptual view, manufacturing equipment (PLC/HMIs), applications (SCADA, historian, data analytics), personnel (via the SCADA and HMI) are interconnected via a unified name space reference architecture. Data is available to all subscribed users at the same time as it becomes available at the UNS broker.

The proof of concept is where an opportunity for the organization to validate the effectiveness of the efforts. The learning and validation enable organizations to understand what works for their use cases, and more importantly what will not work. This "fail fast" method minimizes the cost risks to the scale-out phase.

For less mature organizations or those that have not yet started their digital transformation journey, this may very well be a breakthrough Kaikaku step for them and not only continuous improvement. (Taken from the principles of lean manufacturing, this term refers to a period of radical change that necessitates training and cultural adjustment within the organization.)

Move to Full-Scale Implementation

Following a successful pilot, organizations should focus on scaling solutions across the manufacturing network (buildings, sites), ensuring seamless integration across systems. Leveraging insights and learnings from the pilot phase minimizes risks and enhances the efficiency of full-scale deployment. Scaling often involves implementing digital solutions that standardize quality processes, ensuring regulatory alignment across global operations, and standardized data structures across equipment types for consistent manufacturing network deployment. This standardization of structures, systems, and processes provides certainty in a regulatory environment.

Strive for Continuous Evaluation and Improvement

Digital transformation is not a one-time event but an ongoing journey driven by iterative learning. As such, continuous monitoring and evaluation of implemented solutions are essential to sustaining operational excellence. Organizations should leverage continuous improvement frameworks—such as Plan-Do-Check-Act (PDCA) and Define-Measure-Analyze-Improve-Control (DMAIC)—to remain agile and responsive to new challenges and evolving industry requirements.

PHASED EXECUTION IN DIGITAL TRANSFORMATION

As briefly addressed in the preceding section, once a digital transformation initiative has been proven in a pilot project, the next step is to scale the solution across the organization. This involves ensuring that the solution integrates seamlessly across systems, and leverages the knowledge gained during the pilot to avoid pitfalls experienced during the proof of concept.

In the pharmaceutical industry, scaling may involve implementing a digital solution across multiple production sites to achieve consistent quality and compliance. Figure 3 indicates how the company scaled out the proven solution architecture after the proof of concept was validated. Each disparate site became an instance in the architecture that was created during proof of concept. This makes data available to all data users within the organization in a

Figure 2: Proof of concept

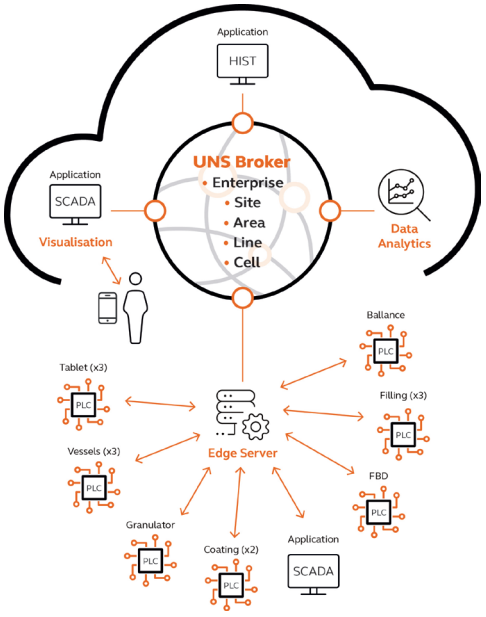
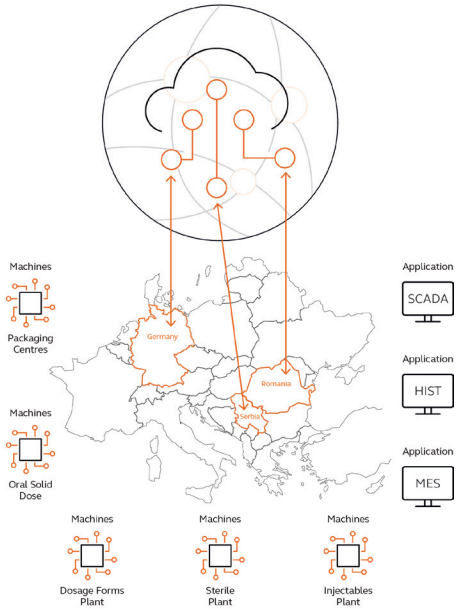


Figure 3: For pharma companies, scaling a digital transformation may involve implementing a solution across multiple production sites, for consistent quality and compliance.



consistent manner across similar equipment and processes across sites and countries.

A typical large-scale execution is composed of two phases: phase A, the initial integration (foundational connectivity) and phase B, advanced integrations. These phases can be understood graphically as shown in Figure 4. Phase A contains foundational processes and enablers to phase B. Phase A is where the business governance and prerequisites, mapping process, physical preparation, physical connectivity, data flow, and capture occur. Within this phase, some insights can be found in the data and visualized/presented to users. Phase B is where the organization has established sufficient data volume and fidelity to progress to advanced predictive analytics and intelligence. Further insights and listing suggested steps are stated within the ISPE Baseline® Guide: Pharma 4.0™.

Phase A

Connect intelligence to the network: This applies particularly to connection of standalone machine equipment, sensors or additional sensors to the manufacturing and/or IT networks. Enable devices to communicate through protocols such as Profibus, Modbus, and TCP/IP. Establish device and sensor connectivity using modern communication protocols, where possible. Ensure all equipment has smart, communication-enabled devices to integrate data collection seamlessly.

Collect data: Aggregate data using robust messaging protocols such as MQTT or communication frameworks like OPC-UA, to ensure reliable and scalable data acquisition. Formulate the data structure to be used for integrating the intelligence; this may be equipment unit-based, such as a centrifuge model or process cell reactor, as well as overheads and packaging lines.

Store and analyze: Use time-series databases, data historians, and data lakes to contextualize data for analytical insights. Implement high-performance data historians to store time-series data.

Analyze this data using dedicated tools to extract insights from the data lake information and to organize it within a data warehouse.

Visualize: Develop user-centric dashboards tailored to stakeholders, such as process engineers, quality managers, shop floor personnel. Present information using relevant platforms for real-time dashboards tailored for the organization's teams (manufacturing, QA, finance, etc.). Data presentation can be done with on-premise, system-specific SCADA, BI tools or a cloud provider platform.

Learn: Assess the information gained to this point, any new knowledge or problem resolutions and if the solution/applications are still "best in class."

Phase B:

Pattern recognition and prediction

Leverage ML algorithms to identify correlations and forecast outcomes based on historical data. Use predictive models for batch yield optimization or equipment maintenance. Develop ML models using contextualized data to detect process anomalies (for example, identifying deviations in media preparation temperature profiles).

Use actionable Insights

Use AI-driven recommendations to optimize process parameters

or identify issues. In pharmaceuticals, these insights must undergo stringent validation to maintain compliance.

Regulatory compliance cannot be understated in the implementation of digital transformation in the pharmaceutical industry. Unlike many other industries, the pharmaceutical sector must adhere to stringent compliance guidelines when applying digital technologies to manufacturing. While predictive analytics and AI can provide valuable recommendations, final decisions about process impacting changes must comply with GxP requirements and be appropriately documented to meet regulatory standards.

For example, recommendations made with AI systems must undergo stringent review and validation before implementation, and must adhere to guidelines such as 21 CFR Part 11 and Annex 11. In fact, any modification to critical process parameters or workflows must be evaluated through formal change control and validation processes. This ensures that modifications align with data integrity principles and meet regulatory expectations.

That said, successful digital transformation not only creates tangible business benefits for the companies in the pharma industry, but it can be an enabler for greater environmental and societal impact (see Figure 1).

Sustainable Digital Transformation

Digital transformation revolutionizes manufacturing, operational efficiency and compliance while playing a critical role in advancing sustainable manufacturing practices. In that way, Pharma 4.0 is not only the industry-specific principles of industry 4.0; it also includes what observers believe will be the hallmark of Industry 5.0: sustainability [8].

Pharmaceutical manufacturing—typically energy-intensive and dependent on complex supply chains—stands to benefit significantly from technologies that reduce environmental impact, optimize resource use, and strengthen supply chain resilience. Digital transformation plays a key role by enabling the development of green factories. These facilities leverage real-time data analytics, machine learning, and the IIoT to improve energy efficiency, minimize waste, and comply with environmental standards such as the EU Green Deal [24] and ISO 50001 Energy Management [25].

There are several direct effects of digital transformation on sustainable manufacturing:

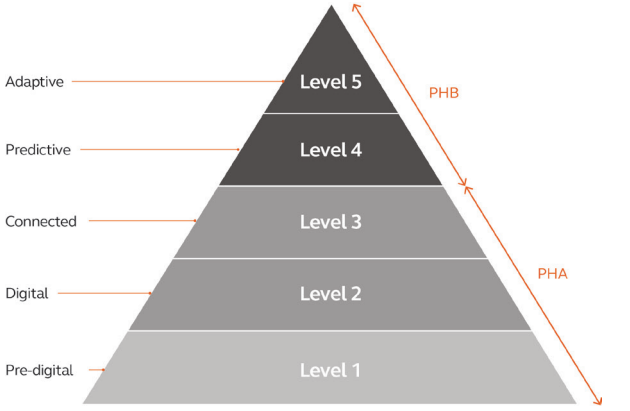
Energy monitoring and optimization

Digital technologies enable real-time monitoring of energy consumption across production lines/buildings. IIoT sensors capture granular data on energy usage, which is analyzed using platforms to identify inefficiencies and recommend energy-saving measures. For example, predictive analytics can optimize heating, ventilation, and cooling (HVAC) and lighting systems, reducing energy costs and emissions.

Circular economy practices

Digital twins can simulate manufacturing processes to minimize waste, enable recycling of by-products, and optimize workflows,

Figure 4: The two phases of full digital transformation



contributing to sustainable operations. These virtual representations allow pharmaceutical companies to reduce material losses, recycle by-products, and implement sustainable waste management systems.

Carbon footprint reduction

Blockchain technology can track the carbon footprint of raw materials and finished products across the supply chain, ensuring transparency and adherence to sustainability goals. Integrated systems also provide automated reporting to comply with regulatory requirements on emissions.

A major pharmaceutical company reduced energy use by 18% over five years by integrating IIoT sensors and AI into its production. This included retrofitting legacy equipment and using AI to optimize batch processing, aligning with sustainability goals.

Supply chain resilience

Pharmaceutical supply chains are uniquely complex, characterized by global sourcing, stringent regulatory requirements, and the need for cold chain logistics. Disruptions caused by geopolitical tensions, pandemics, and climate change amplify the risks, necessitating resilient and adaptive systems.

Digital transformation enhances supply chain resilience through real-time visibility and predictive analytics. Technologies such as blockchain have been adopted for vaccine distribution by pharmaceutical companies to ensure traceability and reduce counterfeit risks. This technology enhances supply chain resilience while meeting stringent compliance requirements.

With predictive analytics, ML models analyze historical and real-time data to forecast supply chain disruptions, such as delays in raw material shipments or changes in demand patterns. This predictive capability allows manufacturers to optimize inventory levels and adjust production schedules accordingly. It also creates a circular supply chain model with which to evaluate supplier practices and prioritize those aligned with sustainability goals.

CONCLUSION

For regulated industries like pharmaceuticals, digital transformation not only helps drive inefficiency out of the process and improve competitiveness, but it also supports enhanced compliance through traceable, automated data flows and minimized manual intervention. This journey, although complex, paves the way for smart, adaptable, and resilient manufacturing ecosystems. The digital transformation journey brings an organization to the ideal digital manufacturing state, where all systems and people are connected in a unified network.

The ultimate vision of digital transformation includes the organization knowing the current state of the business in real time. The organization utilizes predictive analytics through past patterns, current state through ML, and operational adjustment recommendations through AI. With these, stakeholders can better anticipate and adjust to future states proactively. In this ecosystem, manufacturing processes and business layers are seamlessly integrated, and real-time data informs decision-making. The company becomes data-centric because data is integrated, contextualized, and immediately accessible.

Emerging technologies promise further advancements in sustainability and resilience: Quantum computing for optimizing supply chain logistics, AI for developing bio-based materials, and green data centers powered by renewable energy promise to further advance sustainability and resilience in pharmaceutical manufacturing. Blockchain technology will improve end-to-end supply chain traceability and smart contracts, and digital twins will be put to work for predictive maintenance and continuous process improvement. Through digital transformation, pharmaceutical manufacturers can establish themselves as leaders in green manufacturing while building robust, future-ready supply chains that address the challenges of a rapidly changing world.

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