LIFE SCIENCES & HEALTHCARE

STANDARDIZE, SCALE, SUSTAIN: THE MEDTECH MANUFACTURING BLUEPRINT

Achieve standardized, scalable and sustainable manufacturing through digital continuity.

DASSAULT SYSTEMES

EXPERT CONTRIBUTORS

John McCarthy
Life Sciences & Healthcare Industry, Business Value Consulting Senior Director, Dassault Systèmes

John McCarthy has worked with leading companies in the life sciences, consumer products and chemicals industries to deliver software-based solutions to increase the pace of innovation for the past 30 years. An accomplished business strategist, McCarthy is passionate about working with clients to understand their scientific, engineering as well as business challenges and identifying solutions to solve those challenges.

Domhnall Carroll
Chief Executive Officer of Digital Manufacturing Ireland

Domhnall Carroll joined Digital Manufacturing Ireland (The National Advanced Manufacturing Centre) in December 2021, establishing and scaling the organization to be a national showcase, an international exemplar, and a center of excellence for collaborative working on the transformation of manufacturing. Prior to this, Domhnall led the Digital Industries business in Ireland at Siemens, a leading global supplier of manufacturing automation equipment, software and services.

Kim Wilson
Life Sciences & Healthcare Industry, Business Value Consultant Senior Specialist, Dassault Systèmes

Kim Wilson works with MedTech and BioPharma companies to drive better patient outcomes and deliver improved bottom line through the digitalization of end-to-end industry processes, from research and development to manufacturing and supply chain. Kim brings a wealth of experience in manufacturing, product and marketing management, business strategy and consulting across a variety of industries in both Fortune 100 and start-up companies.

Guillaume Vendroux
DELMIA Chief Executive Officer, Dassault Systèmes

Guillaume Vendroux joined Dassault Systèmes in 2016 as CEO of the DELMIA brand. Through the industrial solutions portfolio, he leads the efforts to support all the brand's industries in the digital revolution to come. He graduated from the California Institute of Technology with a Ph.D. in Aeronautics in 1993.

A FUTURE-FORWARD MEDTECH INDUSTRY

In the fast-moving world of life sciences and healthcare, the demand for medical equipment shows no signs of decline. The Medical Technology market (MedTech) is expected to reach $730B by 2026, a 7% climb from $520B in 2021[1], heralding great hopes for medical device makers all around the globe.

However, as many MedTech companies emerged from the COVID-19 pandemic, optimizing production time, eliminating operational silos and dealing with supply chain disruptions have consistently been a major challenge. Other existing difficulties, such as disjointed manufacturing operations, combined with growing regulations, add further pressure.

The business impact of these manufacturing struggles ranges from high defect rates and high volumes of scrap or non-conforming products to increased costs of raw materials, low equipment utilization rates and even worldwide shortages.

Additionally, given the increasing frequency of product recalls, prioritizing product quality becomes crucial. The growing significance of efficiency and quality in medical device production today cannot be understated. Achieving market breakthroughs demands a business transformation.

To effectively manage complications that come their way, MedTech leaders must fully embrace digital technology, transitioning toward standardized, scalable and sustainable manufacturing — the blueprint for success in the transformative era of medical technology.

Read on to discover how digitalization positions medical device manufacturers at the forefront of innovation, driving the industry toward a future where streamlined, scalable and sustainable manufacturing practices are the cornerstone of MedTech success.

[1] *"Pulse of the Industry Medical Technology Report 2023"* by EY (2023)

DRIVERS FOR DIGITALIZATION

While many medical device companies already have highly advanced products and services, a considerable number of them are still in the early stages of digitalizing their business models and supply chains. Some are proceeding cautiously as they grapple with ongoing challenges, which, if left unattended, could hinder their progress and competitive standing in the market.

NAVIGATING REGULATORY COMPLEXITIES

Given the stringent regulations in the MedTech industry, which can be time-consuming and capital-intensive to adapt to, some may struggle to comply.

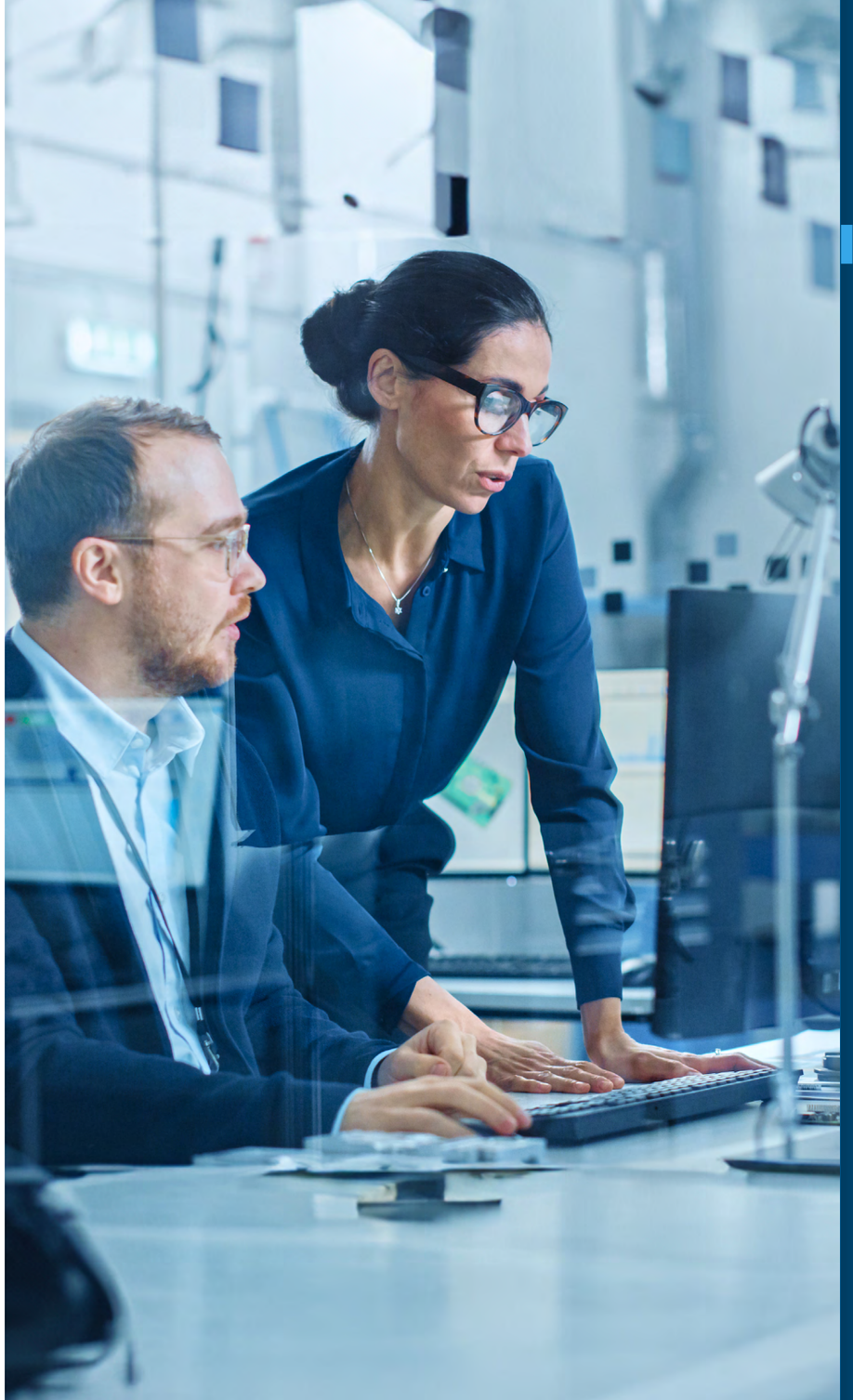
There is real resistance to digitalize MedTech manufacturing due to Computer Software Validation (CSV) — a validation process necessitated by the Food and Drug Administration (FDA) governing the quality of medical equipment before launch. CSV often causes manufacturers to spend 80% of their time on documentation and only 20% on testing[2].

The European Medical Device Regulation (EU-MDR) is another comprehensive regulatory framework that introduces more stringent standards by enhancing device traceability and technical documentation requirements – including clinical evidence, post-market surveillance and conformity assessment – to promote the development of safer and more effective medical devices.

This regulation requires a significant adjustment for the MedTech industry. Manufacturers must reapply for new certificates for their medical equipment, including products that currently exist in the market, to meet stricter safety criteria. "The new recertification system is extremely complex and time-consuming, creating challenges for manufacturers. However, its implementation is essential to meet higher standards for product quality and safety," says Kim Wilson, the Business Value Consultant Senior Specialist at Dassault Systèmes.

In this case, embracing digitalization is not just a strategic choice; it's a fundamental necessity for MedTech companies to successfully navigate the complexities of compliance and change in the wake of the EU-MDR.

[2] "*Understanding FDA's New Approach to Computer Software Validation*" by QAD (Dec 2021)



RISING PRODUCT RECALLS

The surge in the volume of product recalls in the MedTech sector is a cause for concern. News about medical device recalls and lawsuits against manufacturers can spread globally within minutes, especially in the age of social media.

A major quality event can lead to a significant drop of 10% in a company's share price[3], not to mention the long-term implications for a company's brand.

To date, manufacturing defects are identified as the leading cause of recall activity in the first quarter of 2023, accounting for 59 events - 23.4% higher than the previous quarter[4].

Period	Causes of recalls
Q1 2023	Manufacturing defects – 59 events
	Part issues – 38 events
	Sterility – 32 events

Overcoming this challenge may be difficult, so it's vital that manufacturers integrate digitalization from the start. Robust quality control measures must be in place for faster updates and maintenance to detect and remove outdated or non-compliant products.

[3] "*The Digital Era in the MedTech Industry*" by Deloitte

[4] "*Recall Index: 2023 Edition*" by Sedgwick (2023)

MANUFACTURING SILOS EVERYWHERE

Numerous MedTech companies have expanded through mergers and acquisitions, resulting in unsustainable manufacturing silos and one-off manufacturing environments. A siloed setup is problematic for these companies. For example, when they have multiple enterprise resource planning (ERP) systems within one organization, it can cause data inconsistencies and subsequently lead to substantial delays in demand and supply forecasting.

Breaking down silos requires a closer examination of data transparency and the adoption of advanced tools and approaches associated with digital transformation.

Through digitalization, the ability to gain a consolidated view of the entire portfolio can significantly increase, offering enhanced insights into the performance of individual manufacturing sites.

"For companies that have recently acquired or merged with an organization, this is the right moment to assess the digital footprint of both existing and new entities. Even if the structure of manufacturing silos remains unchanged, MedTech leaders can delve into each silo's capabilities and establish connections between different parts of the organization by leveraging virtual twins," says Domhnall Carroll, the Chief Executive Officer of Digital Manufacturing Ireland.

By adopting digital technologies and cultivating a consolidated digital view of manufacturing assets, manufacturers can gain a more viable approach than before.

> "A large medical device manufacturer that relies on our manufacturing execution system has seen impressive results, such as a 100% reduction in transcription errors, a 95% reduction in paper usage, more than a 70% reduction in Work in Process and a greater than 50% time savings on completing Device History Records. Clearly, the benefit of our solutions has a great impact on company efficiencies and cost management.
>
> **— Kim Wilson**
> *Life Sciences & Healthcare Industry,*
> *Business Value Consultant Senior Specialist,*
> *Dassault Systèmes*

THE PRICING PRESSURE IN MEDTECH

The macroeconomic landscape influencing the medical device industry has also been a key driver for digitalization. There is a growing demand for lower-cost solutions from governments, payors and healthcare providers. This push is placing significant pressure on MedTech manufacturers as it implies reduced profitability. They are compelled to offer solutions that not only uphold high standards of quality and innovation but also address the imperative of cost-effectiveness.

Optimizing expenditures without compromising patient outcomes requires MedTech leaders to explore digitalization as a means to enhance operational efficiency. Through digital capabilities such as automation, data analytics and smart manufacturing, companies can streamline production processes, reduce inefficiencies and optimize resource utilization to meet these evolving expectations.

AI, IOT AND BIG DATA IN DIGITAL HEALTHCARE

The rise of advanced technologies such as artificial intelligence (AI), machine learning (ML), internet of things (IoT) and big data has sparked transformative revolutions across various industries, with MedTech being no exception.

The application of AI and IoT ensures minimal errors in production, optimization of clinical trials and resilient supplier networks. The remote management of devices by medical professionals enables more personalized and preventive care.

Automation technology has empowered manufacturers to produce high-quality medical devices with minimal human intervention, simplifying complex tasks like assembling tiny components or performing intricate procedures.

The abovementioned cutting-edge technologies enable the design and development of more complex MedTech devices, both hardware and software components. This, in turn, propels the development of digital health ecosystems.

Ultimately, embracing digitalization in manufacturing medical devices is paramount to achieving standardization, scalability and sustainability. Businesses that refrain from adopting and digitally transforming are at risk of being left behind.

THE ENABLER OF DIGITALIZATION

> Technology is a game-changer, and the crucial aspect of embracing digital technology is getting the people in your company involved in the transformation. The key to success lies in the management's ability to drive technological change across the organization — an aspect equally important as the capabilities that advanced technologies bring.

— Guillaume Vendroux
DELMIA Chief Executive Officer, Dassault Systèmes

Despite apparent industry challenges, medical device makers can focus on adopting new technologies and frameworks to mitigate these threats. Approximately 30% of MedTech companies have succeeded in digital transformations[5], and others can follow suit by selecting the right digital solution.

[5] "*What the Data Tells Us About Digital Transformation*" by Boston Consulting Group (2021)

DIGITAL PRECISION FOR EVERY DEVICE

From the design phase to production and quality control, digitalization ensures a seamless flow of information, fostering collaboration and communication across different stages of the manufacturing process. This not only accelerates production timelines but also enhances precision and quality — critical factors in the MedTech sector, where accuracy can be a matter of life and death.

In addition, the transformative virtual twin technology empowers manufacturers to go beyond creating just a digital replica of a physical product or system. It fosters virtual twin experiences, which lets them visualize, model and simulate the entire environment throughout the product development lifecycle.

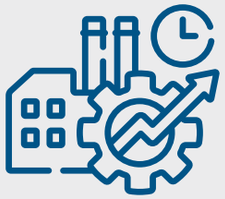
Data-driven decision-making is also another essential part of the equation. Understanding how data is developed, collected, handled and visualized is crucial for gaining a coherent view of the entire production process and flow.

By having the knowledge and know-how of data use and visualization, MedTech leaders can gain confidence in making informed decisions. Discussing the provenance of data from the early stages is fundamental to establishing good data transparency.

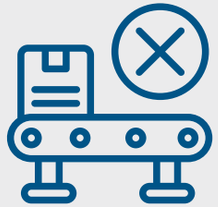
Manufacturers can then use the data without the need for re-validation, eliminating the challenge of making faster and better decisions. Similarly, when an end-to-end view of a process or a product through a value stream is available, it instills confidence that the data adequately covers all essential aspects. Individual data origin is crucial, as it ensures that the context of the data is correct. This confirms that the company is examining all the necessary data to have a well-informed view of a particular issue or performance level.

DESIGNING FOR MANUFACTURING EFFICIENCY

Connecting across the entire product lifecycle on a single digital platform is absolutely crucial. By doing so, manufacturers can:

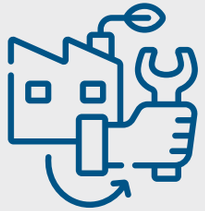


Ensure that engineers design for manufacturing — for more efficient production and lower costs



Understand and address issues such as breakage during assembly to reduce scrap production and achieve improved sustainability

Plan more effectively, manage resources and address issues such as material availability and equipment utilization



Achieve better coordination of routine maintenance, calibration and quality checks without disrupting overall production

"We've seen many examples in MedTech where reducing waste and establishing shorter supply chains significantly impact patient outcomes. This has been particularly evident in orthopedics and areas such as catheters and guidewires for intervention delivery systems. The accelerated delivery of high-quality products in recent years is due to the adoption of advanced manufacturing technologies, as opposed to expanding factories. This positive outcome not only enhances efficiency but also improves overall costs," states Domhnall.

Having full traceability within the production line is also fundamental for manufacturing efficiency. "With image recognition and image analysis capabilities, manufacturers can ensure that parts have been designed, put together or manufactured correctly right from the start. This helps reduce high defect rates and meet required quality standards," explains McCarthy.

THE 3DEXPERIENCE PLATFORM IN ACTION

The **3D**EXPERIENCE® platform provides the ability for people to collaborate effectively across different parts of their organization in their business.

"That collaborative ability allows people in different manufacturing facilities – let's say, in the US, Germany and China – to see the differences between those facilities and how they perform various operations," McCarthy adds.

This visibility promotes close collaboration among stakeholders to address emerging issues and understand why one facility might outperform another in terms of KPIs, including output, productivity, quality and safety.

In addition, our virtual twin technology allows MedTech companies to plan and create a virtual model of the manufacturing line and optimize it in advance of building the actual line.

Here's a good question to ask yourself: Does it make more sense for our company to have a straight-line approach to the assembly process, or does it make more sense for us to have a U-shaped line to improve output as well as worker performance and safety? Observing such instances – how the lines are set up in China, for example, and comparing that to how the lines have been set up in the US – will drive manufacturers to learn from one another, facilitating the design of more efficient manufacturing lines and ultimately enhancing operational efficiency.

On top of that, the collaborative capability of the **3D**EXPERIENCE platform connects manufacturing teams to R&D teams who are handling designs. This enables a faster and more efficient design transfer process.

This establishes a feedback loop for the engineers responsible for product design, ensuring improved quality and manufacturability. It also facilitates the response to dynamic changes, such as supply chain disruptions caused by component shortages, pandemics, geopolitical uncertainties and regulatory changes.

> "There are constant disruptions experienced in the supply chain in recent years. This calls for a rapid response from the manufacturing, design and engineering teams to make changes to designs and find solutions for part supply issues.
>
> **— John McCarthy**
> *Life Sciences & Healthcare Industry, Business Value Consulting Senior Director, Dassault Systèmes*

THE POWER OF DIGITALIZATION

With digitalization in place, MedTech leaders are well-positioned to lead the market through streamlined, scalable and sustainable manufacturing practices. Here's how:

STANDARDIZE FOR SUCCESS

Streamlining and simplifying operations across medical device manufacturing can be accomplished through three integrated capabilities on the **3DEXPERIENCE** platform. These allow MedTech organizations to standardize and scale manufacturing operations while becoming more sustainable, as highlighted below:

Production Execution Excellence	Quality Execution Excellence	Material Synchronization Excellence
Optimize performance through coordination of production activities such as orders, inventory and quality, while improving visibility, control and synchronization of global production	Embed and integrate quality into logistics and production workflows to simplify monitoring and remediation tasks	Establish a seamless connection between raw materials, consumables, and parts in the warehouse with those utilized during the assembly process on the shop floor
	Generate a blueprint for one manufacturing facility and then use this standardized blueprint across other facilities	
	Standardize work instructions and shop floor equipment integration while harmonizing quality control	Manage the flow of outgoing final materials from the shop floor to the warehouse for shipment while minimizing idle inventory

"In streamlining MedTech manufacturing, a crucial aspect is building core models of processes that are supported by unified software to ensure that best practices are standardized," states Vendroux.

This ensures consistency across various sites and business units within a MedTech company. Scalability is inherent in this approach, as it eliminates the need to reinvent processes at every site.

SCALING UP WITH AGILITY

To react quickly to market needs and achieve scalability within the industry, MedTech leaders can rely on Dassault Systèmes' Made to Cure for Medical Device solution powered by the **3DEXPERIENCE** platform.

Made to Cure enables medical device makers to:

Validate and document manufacturing process plans from engineering all the way through to manufacturing

Go through the complete fabrication sequence, directly visualizing the corresponding product buildup in 3D

Leverage powerful, intuitive capabilities to identify and address potential assembly issues

Define, optimize and validate manufacturing process plans in a 3D environment through virtual twin

COLLABORATE AT THE CENTER OF EXCELLENCE

Companies with tuck-in acquisitions often come up with their own environments and approaches to both designing and manufacturing medical devices, and that generates multiple challenges for the organization.

Dassault Systèmes manufacturing solutions help MedTech companies effectively:

Conduct thorough audits of various manufacturing processes for different pieces of equipment

Establish a single source of truth to standardize operational procedures across manufacturing organizations by templatizing processes

Customize and tailor the common template to align with the unique processes of individual facilities worldwide

Learn from one manufacturing facility and use the insights gained to improve global operations at other manufacturing plants

These solutions enhance efficiency at every stage of the supply chain and production journey. Manufacturers can seamlessly conduct end-to-end planning and optimization within a unified digital environment accessible to stakeholders globally, across all departments.

INNOVATE FOR QUALITY EXCELLENCE

Inadequate sterilization of medical devices, compromised product quality and software issues are some of the common factors for increasing product recalls. These can be managed with Dassault Systèmes' Manufacturing Execution System and Quality Execution System solutions, which allow you to:

Collect product and process data for genealogy and traceability requirements	Utilize customized dashboards with key performance indicators (KPIs) and real-time monitoring	Reduce the cost of quality with expedited identification, analysis and resolution of quality issues throughout the manufacturing process	Set predefined quality parameters and establish inspection plans with access to detailed information for rework plans in case of deviations	Embed and integrate quality into logistics and production workflows to simplify monitoring, remediation tasks and forward analytics	Apply built-in quality measurement, in-line statistical process control (SPC) and error-proofing to detect and prevent quality defects within production process execution
Perform quality inspections based on pre-defined parameters and inspection plans	Capture prompts and electronic signatures during manufacturing	Utilize statistical-based methodology to prevent quality problems	Automatically generate manufacturing reports with complete traceability	Request, approve and perform final inspections of any reworks	

THE VIRTUAL TWIN AS AN ALLY

Navigating regulations in one of the most stringent industries can be highly demanding. However, virtual twin technology can empower MedTech companies by helping them speed up innovation – in terms of regulatory compliance and product development – in a scalable and sustainable manner.

Integrating the virtual twin into manufacturing operations aids MedTech leaders in achieving compliance with:

21 CFR PART 820
QUALITY SYSTEM REGULATION (QSR)

The virtual twin allows companies to model their production facility and perform simulations to determine the best output. This eliminates bottlenecks and potential quality issues.

21 CFR PART 11
ELECTRONIC SIGNATURES

Companies gain better control of their operations through production traceability enabled by the virtual twin. An electronic signature can be created and captured during the production process, which contributes as a major auditing step in manufacturing.

> “By using the virtual twin, you can alleviate any disconnects or other unfavorable scenarios that might arise — ones that would be difficult to foresee without this technology. This capability is crucial to ensuring compliance with industry regulations as a whole.
>
> **— Kim Wilson**
> *Life Sciences & Healthcare Industry, Business Value Consultant Senior Specialist, Dassault Systèmes*

Following the newly published guidance on computational modeling and simulation (CM&S) by the FDA, the virtual twin technology again emerges as a pivotal ally, empowering MedTech leaders to:

Minimize animal testing:
Reduce the use of animal testing by using virtual twins early in product development

Amplify clinical experience:
Gain more clinical expertise, refine product design and explore edge cases that would traditionally be left untested

Optimize validation strategies:
Support the verification and validation (V&V) phase in product development

Elevate submission standards:
Build a stronger case through the use of in silico evidence for regulatory submission

Accelerate business success:
Drive faster commercial success, achieve substantial cost reduction and enhance the safety of new products

Clearly, in silico methodologies present a revolutionary approach to predicting the success and potential setbacks of newly developed medical devices.

To fulfill the FDA's vision of virtual clinical studies, virtual physiological patients and personalized medicine, MedTech companies need access to robust CM&S tools — precisely what Dassault Systèmes' virtual twin experiences offer.

> "Utilizing virtual twins speeds up the process of test validation and simulating solutions for shop floors, leading to a faster transition to peak efficiency. As a result, in the ramp-up phases, there is a considerably shorter timeframe to reach optimal value or, at the very least, approach the asymptotic value.
>
> **— Guillaume Vendroux**
> *DELMIA Chief Executive Officer, Dassault Systèmes*

SCHEDULING FOR SUSTAINABILITY

One of the things that has become extremely important within the MedTech space that was evident during the COVID pandemic is being able to deliver the devices that patients and hospitals need on time, in full and in a sustainable manner.

Today, through Dassault Systèmes' virtual twin experiences on the **3DEXPERIENCE** platform, simulating, operating and enhancing manufacturing processes for sustainability is possible. This involves refining production flows as well as identifying and eliminating bottlenecks before they occur.

"Our production planning and scheduling solutions let you consider all your resources to make sure production capabilities are using one collaborative environment. You can model and simulate every detail, from manufacturing equipment and skilled operators to order timelines and raw material availability. Everything is considered, even unexpected equipment maintenance and vacation schedules," said Wilson.

These transformative tools facilitate medical device manufacturers in reaching:

35% lead time reduction

43% scheduling cycle time reduction

18% productivity gain

80% manual documentation work reduction

40% inventory and safety stock reduction

25% forecast accuracy

54% extra hours reduction

30% set-up time reduction and lot size optimization

> "Our innovative tools empower you to be more efficient, where you can do more with less. This involves eliminating non-quality materials, waste and time lost on the shop floor. By enhancing efficiency and eliminating excess, you naturally contribute to improving the sustainability of your operations and reducing your carbon footprint.
>
> **— Guillaume Vendroux**
> *DELMIA Chief Executive Officer,*
> *Dassault Systèmes*

SCALING HEIGHTS IN MEDTECH MANUFACTURING

> “Achieving business goals without harnessing advanced technologies is extremely difficult, if not impossible. Modeling and simulation can accelerate manufacturers’ response to changing market demands, whether using simulation in a greenfield environment or assessing the impact on existing manufacturing assets in the supply chain. The competitive advantage gained through simulation is what sets these technologies apart.
>
> **— Domhnall Carroll**
> *Chief Executive Officer of Digital Manufacturing Ireland*

Moving forward, the industry’s priorities are shifting to innovating digital products and services, specifically in digitalizing the supply chain, support functions and next-generation sales. These advancements will amplify positive outcomes by further reducing waste, optimizing supply chains and accelerating production.

Similarly, the use of simulations in designing new production lines has accelerated the qualification process, ensuring that medical products reach patients faster.

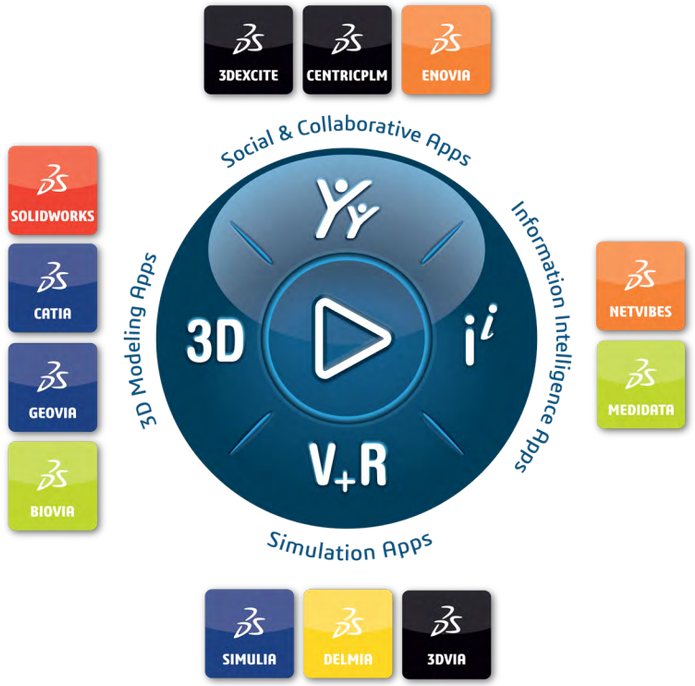
All in all, the digitalization of MedTech manufacturing is a driving force for operational efficiency and transformative patient experiences. The powerful capabilities of virtual twin technology and advanced solutions on the **3D**EXPERIENCE platform unlock limitless possibilities, ushering in a new era of standardized, scalable and sustainable MedTech manufacturing.

Discover our solutions

Our **3D**EXPERIENCE® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating virtual twin experiences of the real world with our **3D**EXPERIENCE platform and applications, our customers can redefine the creation, production and life-cycle-management processes of their offer and thus have a meaningful impact to make the world more sustainable. The beauty of the Experience Economy is that it is a human-centered economy for the benefit of all –consumers, patients and citizens.

Dassault Systèmes brings value to more than 300,000 customers of all sizes, in all industries, in more than 150 countries. For more information, visit **www.3ds.com**.



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