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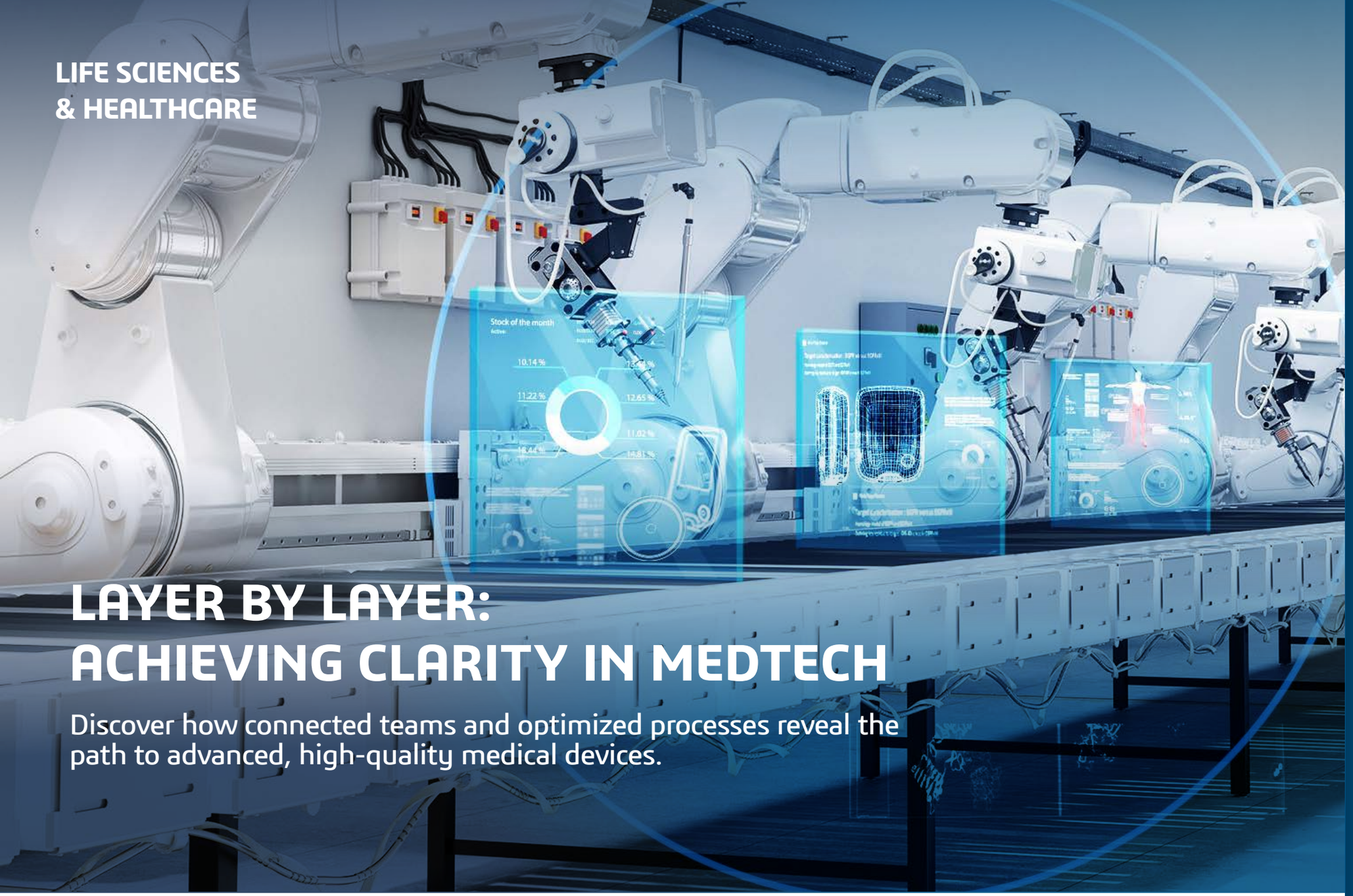


LAYER BY LAYER: ACHIEVING CLARITY IN MEDTECH

Discover how connected teams and optimized processes reveal the path to advanced, high-quality medical devices.

goengineer

DASSAULT SYSTEMES

OUR MEDTECH EXPERTS

John McCarthy

Life Sciences & Healthcare Industry Business Strategy Senior Director Dassault Systèmes

John McCarthy has worked with leading companies in 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 and business challenges and identifying solutions.

Stephane Declee

ENOVIA Chief Executive Officer Dassault Systèmes

Stéphane Declee has 25 years of experience in engineering and executive leadership at Dassault Systemès, where he began his career in 1991 as a research and development software engineer. In his current role, Declee is responsible for all aspects of the ENOVIA brand strategy, portfolio and business operations. He is also a member of Dassault Systemès' Global Executive Management team.

Darcy Sheerin

ENOVIA Industry Process Expert Dassault Systèmes

Darcy Sheerin has extensive experience in the life sciences sector, with a background in clinical environments and healthcare institutions. She has held leadership positions in management and strategic marketing, contributing to healthcare innovation through product development and team leadership. Sheerin excels in market research and customer relationship management, consistently achieving significant results in the industry.

LAYER I

MERGE:

Aligning Perspectives

ALIGNING PERSPECTIVES THROUGH TRANSPARENT COLLABORATION

Innovation is the pathway to delivering better treatments and transforming patient lives. Teams within a MedTech company may have the knowledge and expertise to innovate but often struggle to meet the larger goals of delivering value to the wider organization.

One major obstacle is the lack of connection in the collaboration process. This is due to the implementation of many disconnected apps to exchange ideas, making it challenging to organize and apply feedback after initial discussions. As a result, early ideas can get lost or overlooked as a project progresses.

Another challenge is siloed workflows, where engineering, quality, manufacturing and regulatory teams work separately — leading to blind spots, misaligned objectives and costly delays.

28%
of engineers work with outdated information[2]

80%
of design issues are discovered late in the development process[2]

300x
higher costs of fixing late-stage design issues than addressing them early on

A more agile, connected approach is needed — one that enables **collaboration, shared insights and project management** in one place to align perspectives effectively and thereby boost productivity.

> “In the rapidly evolving MedTech field, collaboration is not just beneficial, it is essential. The intricate nature of modern medical devices, which integrate multiple systems and digital connectivity, demands a shift away from outdated, manual and siloed processes.”
>
> — Stephane Declee
> ENOVIA Chief Executive Officer, Dassault Systèmes

[2] “What’s the Cost of Poor Collaboration?” By Tech Clarity (2020)

The cloud-based **3DEXPERIENCE** platform supports innovation by allowing teams to share knowledge, prioritize ideas and transform them into novel medical devices. The platform transforms market opportunities into marketplace advantages through a unified digital environment. Organizations gain several key advantages such as:

Full traceability from ideation to commercialization

The **3DEXPERIENCE** platform facilitates access to relevant project information, enabling seamless collaboration across functions. Engineers, designers and regulatory experts work from a shared data model for complete traceability. This ensures that the voice of the customer is translated into actionable system requirements for a medical device.

Teams can share knowledge, submit ideas and provide real-time feedback, thus streamlining the verification and validation process. "This eliminates the inefficiencies common in paper-based documents or static electronic apps, often leading to lost ideas throughout the project," says Darcy Sheerin, ENOVIA Industry Process Expert at Dassault Systèmes.

By utilizing project templates encapsulating best practices, teams drive compliance with corporate standards while maintaining agile project management. Teams can quickly compile dossiers with real-time data and ensure all risk management and regulatory compliance criteria are accurately covered. Additionally, full traceability across the product lifecycle makes certain that all stakeholders are aligned on compliance goals. This leads to improved regulatory submissions, such as FDA or Medical Device Regulation (MDR), and faster market entry.

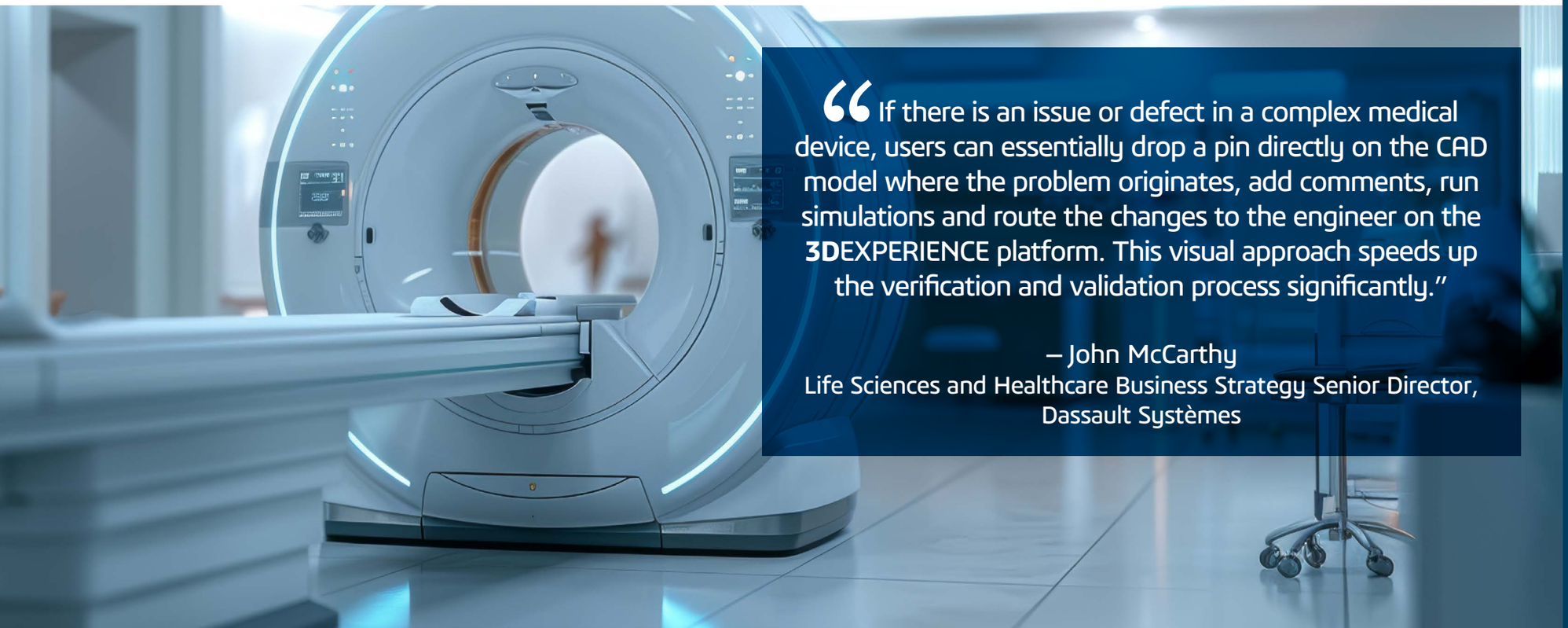
Streamlined bill of materials (BOM)

Typically, various departments manage their own BOMs, leading to discrepancies that complicate the design and production process. By centralizing the BOM across disciplines, the **3D**EXPERIENCE platform ensures that all teams work from a single version of the truth.

Cross-departmental visibility significantly reduces the risk of errors, enabling streamlined collaboration between product development and quality teams. This ensures that changes are evaluated throughout the entire medical device lifecycle, maintaining alignment at every stage.

Data-driven portfolio governance

The **3D**EXPERIENCE platform enables data-driven portfolio governance, empowering teams to manage tasks, deliverables and milestones through real-time updates. By identifying risks like validation delays or regulatory bottlenecks early, teams can meet regulatory compliance deadlines, such as pre-market submissions and post-market surveillance.



> "If there is an issue or defect in a complex medical device, users can essentially drop a pin directly on the CAD model where the problem originates, add comments, run simulations and route the changes to the engineer on the **3D**EXPERIENCE platform. This visual approach speeds up the verification and validation process significantly."
>
> – John McCarthy
> Life Sciences and Healthcare Business Strategy Senior Director, Dassault Systèmes

CASE IN POINT

Transforming collaboration into intuitive devices

Novo Nordisk, a leader in diabetes care, faced the challenge of ensuring the reliability and performance of insulin pens under various conditions. To address this, the company partnered with SIMULIA's Dassault Systèmes simulation experts to develop advanced simulation methodologies. However, the true success of the project was not just in the simulation capabilities but in the seamless collaboration between the two teams.

This partnership enabled Novo Nordisk's engineering and simulation teams to work closely with experts, continuously refining their models to capture the complex behavior of materials under stress. The exchange of knowledge and expertise led to improved design accuracy and deeper insights into the insulin pen performance and manufacturing processes. By integrating simulation-driven testing with manufacturing data, Novo Nordisk could optimize the snap-fit model design to be safe and reliable to meet patient needs.

Read the full story here.

LAYER II

TEST:

Revealing Insights

REVEALING INSIGHTS USING MODELING AND SIMULATION

With a rise in demand for innovative healthcare, efficiency is essential to accelerate time to market while ensuring the highest quality standards and regulatory compliance.

The key challenge lies in the complexity of medical devices. Modern devices now consist of multiple interconnected systems and subsystems that must perform flawlessly in diverse and unpredictable environments. Traditional physical testing, once the backbone of product validation, is no longer sufficient to meet the need for speed and patient safety.

Integrating **modeling and simulation capabilities** drives faster, more efficient methods for designing, testing, and validating medical devices, providing insights that reveal potential issues early.

> "Simulation has long been a valuable tool, but its acceptance has grown due to improved data pool of knowledge and increased trust. This evolution accelerates design iterations, reduces risks with new material, and enhances collaboration among all teams."

– Darcy Sheerin
ENOVIA Industry Expert, Dassault Systèmes

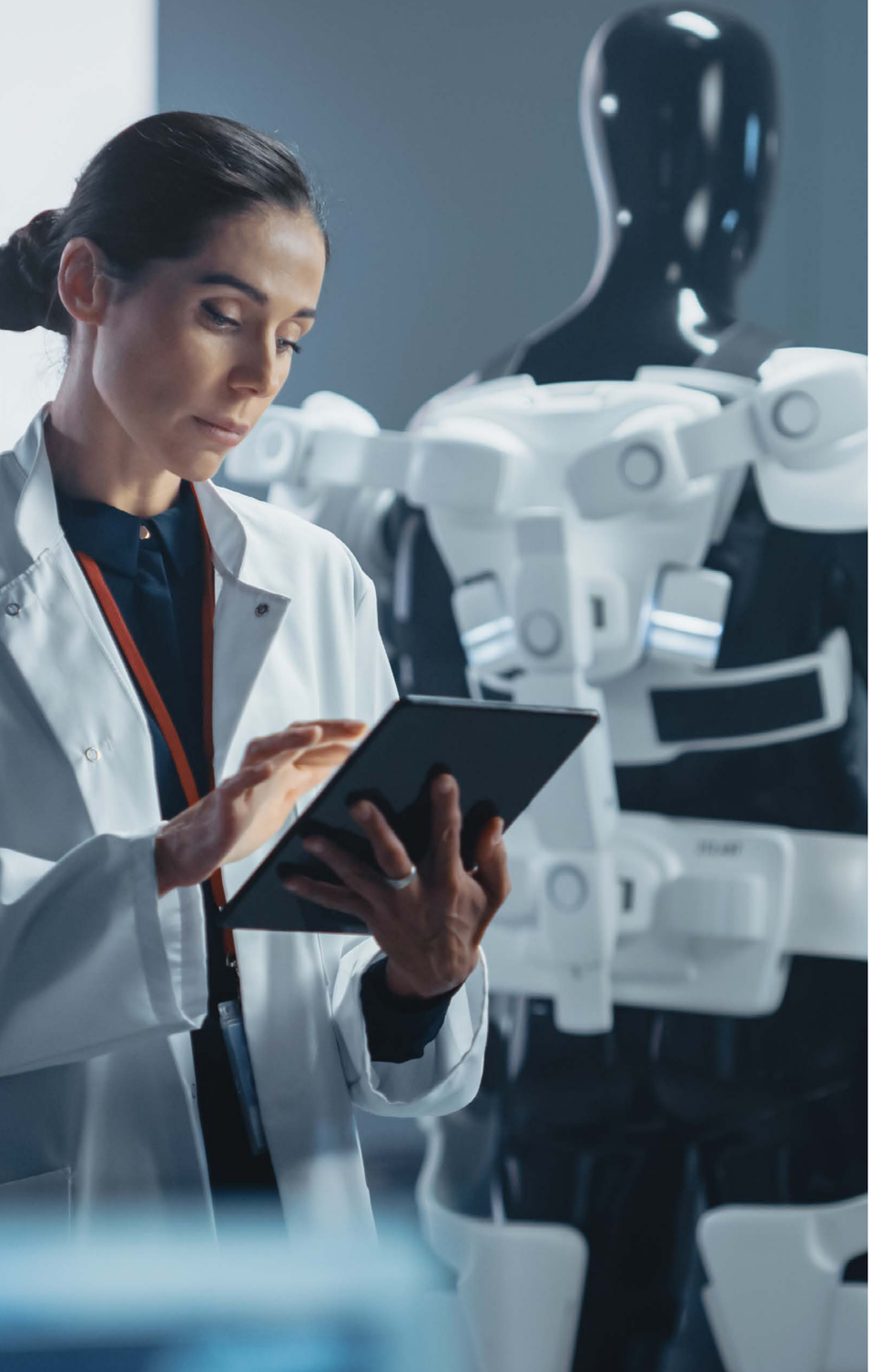
The **3DEXPERIENCE** platform democratizes simulation across disciplines — from CAD designers to systems engineers — allowing multiphysics and multiscale simulations to explore and validate design concepts across structural, fluidic, electromagnetic and thermal domains. A unified digital thread also enables real-time simulations to:

Uphold better quality

44% of voluntary recalls could be avoided with better design controls in place[3]. Simulation goes beyond reactive testing, offering a proactive approach to risk management. By modeling how devices perform under various conditions, in different environments and for diverse patient populations, teams are able to predict and mitigate potential issues early in the development process.

- **Risk prediction**: Through simulation, potential problems like mechanical fatigue or electromagnetic interference are identified before physical production begins.
- **Continuous improvement**: Testing various product design iterations allows companies to refine devices and improve performance and patient safety. This is also applied once the product is brought to market with a design continuously optimized using patient feedback.
- **Compliance assurance**: Integrating simulation with regulatory frameworks ensures devices remain compliant throughout the development lifecycle, even as designs evolve.

[3] "Implementing design controls: Medical device quality, compliance, & traceability" by Kapstone Medical (2024)



Reduce physical testing

Virtual simulation reduces the need for physical prototypes by allowing companies to simulate real-world conditions well before a device reaches manufacturing.

- **Engineering efficiency**: Early detection of design flaws and performance issues saves time and reduces late-stage changes.
- **Patient experience**: Advanced simulations, including realistic human body simulations, ensure that devices are tailored to the patient's unique anatomy and disease state, enhancing both device efficacy and patient outcomes.
- **Cost effectiveness**: Running multiple iterations of virtual tests accelerates innovation cycles without the need for prototypes with every design change.

Meet regulatory compliance

Simulation ensures that the entire product lifecycle is handled efficiently, adhering to industry best practices and regulatory requirements. This reduces the risk of compliance issues during audits or regulatory reviews.

- **Regulatory confidence**: Simulation tools present highly detailed evidence for medical devices to meet regulatory requirements, reducing the likelihood of delays or rejections.
- **Quality control**: Early detection of potential failures ensures devices meet safety and quality standards, minimizing the risk of product recalls.

CASE IN POINT

Simulation testing for performance and compliance

The ENRICHMENT project is a groundbreaking collaboration between Dassault Systèmes and the FDA that exemplifies the transformative impact of simulation on advancing medical device innovation. This initiative integrates in silico clinical trials (ISCT) to effectively model and predict the behavior of medical devices within simulated patient populations.

By utilizing detailed virtual twins — crafted from real patient data, medical imaging and physiological models — experts simulate the effects of medical devices or treatments on diverse patient profiles. This approach captures critical variations in anatomy, genetics and disease states, enabling the creation of personalized simulations that closely mimic real-world scenarios. ISCTs harness virtual simulation to predict clinical outcomes and optimize treatment protocols, significantly reducing the reliance on traditional human trials.

> "By working with the FDA, we have demonstrated how in silico data can augment filings and shorten the time required to recruit smaller patient populations, ultimately speeding up clinical trials and bringing life-saving breakthrough treatments to market faster. This emphasizes that simulation is not merely an ancillary tool but a cornerstone of modern medical innovation. "

— John McCarthy
Life Sciences and Healthcare Business Strategy Senior Director,
Dassault Systèmes

Learn more here.

LAYER III

OPTIMIZE:

Driving Sustainability

DRIVING SUSTAINABILITY USING INNOVATION INTELLIGENCE

With increasing pressure from regulatory bodies and eco-conscious consumers, MedTech companies must design, develop and manufacture devices that meet both the needs of the patient and the needs of the planet.

Companies that put sustainable product development into practice stand to benefit from robust operations in a competitive environment, capture existing market demand to establish growth and maintain a leadership position in the industry as an organization that can deliver new sustainable products and services innovation to customers.

The **3DEXPERIENCE** platform is uniquely positioned to help leading MedTech companies optimize the product development process and embed sustainability into the DNA of their organizations. Here's how:

Lifecycle assessment-driven sustainability

Sustainable Innovation Intelligence, the **3DEXPERIENCE** platform's lifecycle assessment (LCA) solution, combines the most up-to-date data with a multi-discipline collaborative platform to support an iterative eco-design framework. This science-based, standardized methodology allows companies to assess the environmental impact of products throughout their lifecycles to innovate in new ways while reducing their environmental impact. The platform enables real-time evaluation of material choices, energy consumption and the overall carbon footprint measurements of a medical device from early-stage design to end-of-life disposal.

- **Eco-design framework**

This approach integrates sustainability into the design and development process across products, services and more. In addition to focusing on sustainability, it also recognizes the importance of profitability and enhancing product features for increased returns.

- **Ecoinvent database**

As the most consistent and transparent lifecycle inventory database globally, ecoinvent supports comprehensive environmental assessments. Maintained by the ecoinvent Association, it contains over 18,000 datasets modeling human activities and processes, enabling users to trace the environmental impact of products across the supply chain. This transparency facilitates informed decision-making throughout design and development.

> "The platform's capabilities provide data-driven insights that inform and improve future product iterations. With historical data accessible throughout the lifecycle, companies can refine designs, reduce waste and enhance sustainability with each new device."
>
> — Darcy Sheerin
> ENOVIA Industry Expert, Dassault Systèmes

Circularity in medical device development

As the European Green Deal aims to make the EU climate-neutral and sustainable by 2050, industry-wide participation is crucial, reflecting the need for circularity in MedTech product development[4].

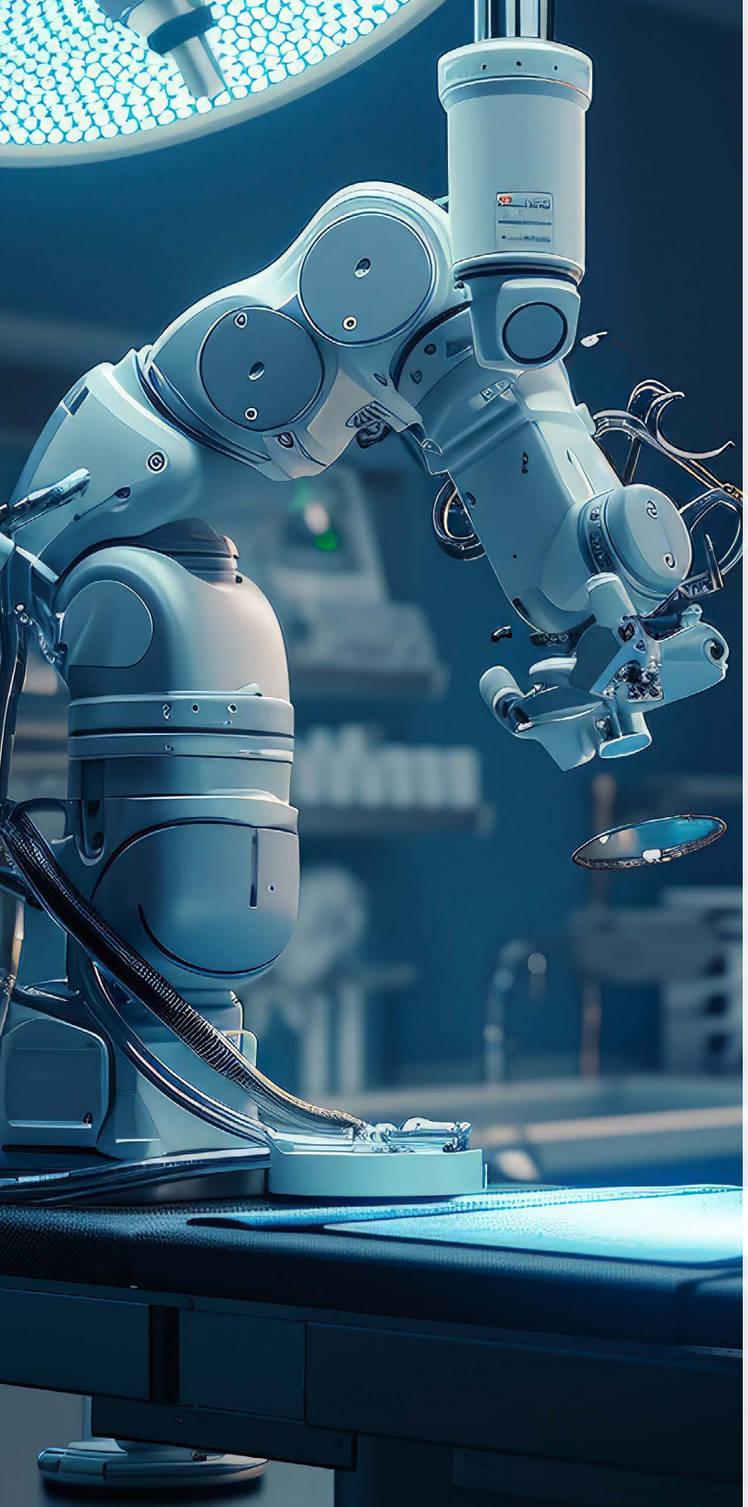
The updated EU Medical Device Regulation (MDR 2017/745) mandates lifecycle tracking from design to disposal, driving the adoption of circular processes from sustainable material selection to innovative take-back programs. This requires collaboration among stakeholders, including regulatory bodies and manufacturers, to establish a cohesive framework supporting circular product development.

Single-use devices (SUDs), while convenient and infection-resistant, often end up as incinerated waste. Currently, most IFUs (Instructions for Use) only outline standard disposal, but new directives could require detailed guidance on decontamination and recycling, aligning waste management with sustainability goals. While legislative support for SUD recycling remains limited due to challenges in waste classification and regional health regulations, for some devices, reprocessing offers a viable solution. The following are alternative ways to adhere to sustainability regulations in MedTech development.

Six pathways to sustainable MedTech

- Materials selection: Consider bio-based alternatives and fewer materials to simplify recycling.
- Device design: Minimize size and weight to reduce emissions tied to material use and transportation.
- Manufacturing process: Adopt energy-efficient practices and explore additive manufacturing to cut waste.
- Packaging: Reduce waste through recyclable, compostable packaging and limit petroleum-based plastics.
- Distribution: Optimize manufacturing and warehousing to minimize transport distances
- Disposal and recycling: Shift from single-use to reusable designs where feasible; explore take-back programs for refurbishment.

[4] "From Linear to Circular – Sustainability in the Medical Device Industry" by KPMG (2023)



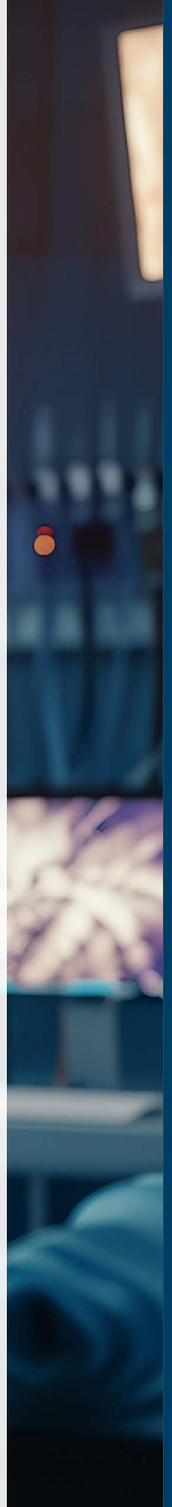
CASE IN POINT:

The future of sustainable MedTech innovation

Consider a leading global MedTech company that produces billions of syringes annually, critical for delivering vaccines and medications worldwide. Faced with increasing sustainability demands, the company aimed to reduce plastic waste in its syringes while maintaining safety and efficacy. The challenge was twofold: Could bioplastics be incorporated and could traditional plastic usage be minimized without compromising product integrity?

The company partnered with Dassault Systèmes to implement sustainability solutions and simulation capabilities by assessing the viability of bioplastics, ensuring these sustainable alternatives would still maintain medication integrity. Where bioplastics proved unsuitable, the company optimized traditional plastics for minimal material usage without sacrificing performance.

The company leveraged advanced simulation tools to model the long-term performance of syringes, identifying material reduction opportunities and preventing potential product recalls.



THE COMPLETE PICTURE

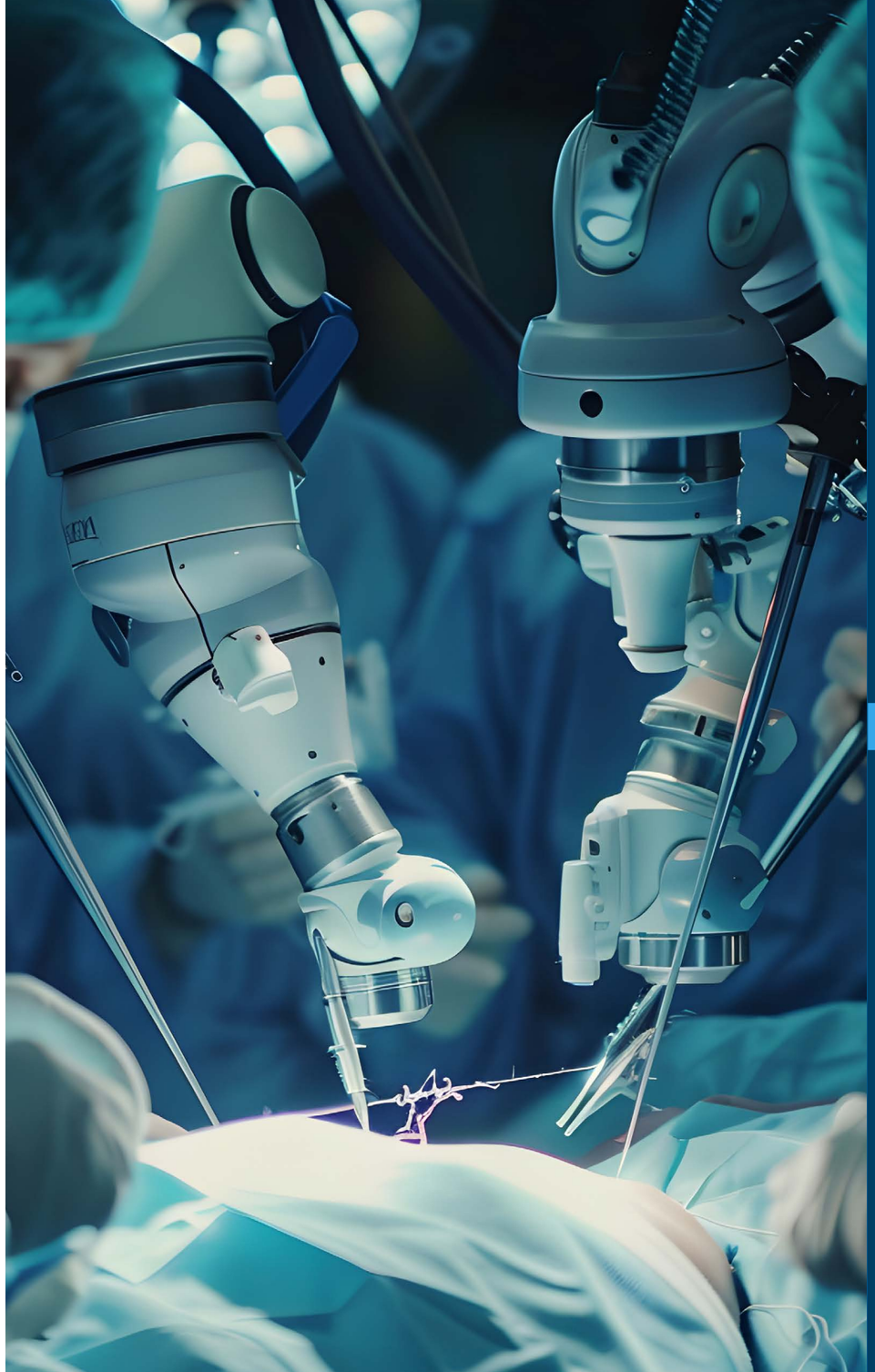
The path to innovation is best navigated through a connected approach anchored on three key layers — collaboration, simulation and sustainability. Whether it is developing wearable medical devices, surgical robots or continuous glucose monitors, the **3D**EXPERIENCE platform drives advanced, high-quality medical devices that significantly improve patient care.

A unified data-driven portfolio view of projects connects patients, designers, engineers, quality experts and manufacturing teams on a single platform, ensuring seamless collaboration throughout the entire product lifecycle. This accelerates the development and market entry of innovative devices while simulation capabilities ensure compliance with strict regulatory guidelines on design controls and design history.

> "By harnessing the power of collective intelligence, we can accelerate the development of groundbreaking solutions that enhance patient care and drive innovation at an unprecedented pace."

— Stephane Declee
ENOVIA Chief Executive Officer Dassault Systèmes

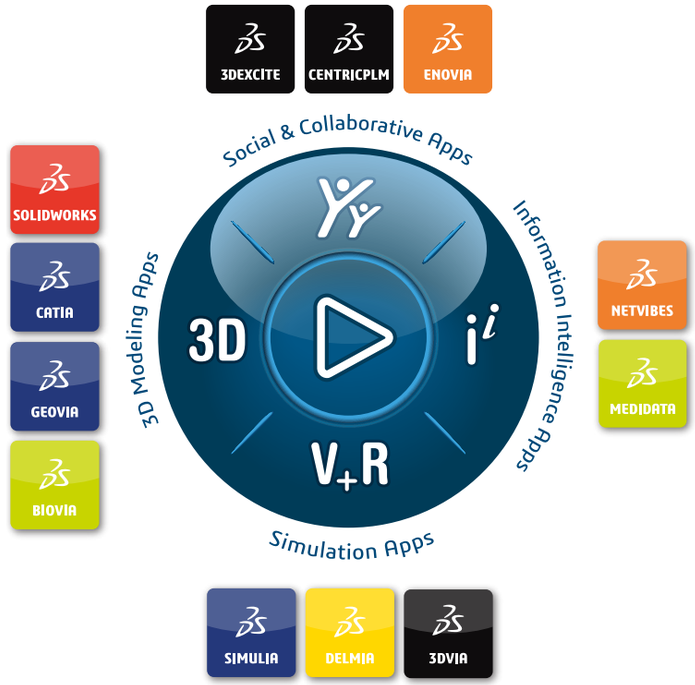
Ready to unlock faster, better and more sustainable innovations in patient care? Explore the full Industry Solution Experiences here.



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

Dassault Systèmes 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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