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CLAIRE BIOT
Life Sciences
& Healthcare Industry,
Vice President,
Dassault Systèmes

Biot leads the Life Sciences & Healthcare industry organization at Dassault Systèmes to drive long-term growth in the healthcare ecosystem. She helps companies leverage the virtual twins to achieve medical practice excellence and value-based care. Biot aims to help companies deliver more patient-centric solutions better and faster through sustainable innovations. She holds an MSc in Engineering from Ecole Polytechnique, an MSc in Biological Sciences from the Watson School of Biological Sciences and a Ph.D. in Immunology from Institut Pasteur, France.

ELITE EXPERTS



KARL D'SOUZA
SIMULIA Life Sciences
& Healthcare Industry
Process Director,
Dassault Systèmes

With over 20 years of experience in computational modeling and simulation, D'Souza is highly skilled in technology consulting, product management and business development – especially in the areas of simulation-based solutions. D'Souza is currently focused on driving the success of Dassault Systèmes' portfolio of modeling and simulation solutions for Life Sciences & Healthcare and has led many transformative novel digital health solutions for the industry.



JOHN MCCARTHY
Life Sciences
& Healthcare Industry,
Business Strategy
Senior Director,
Dassault Systèmes

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.

EXTERNAL PARTNERS



EDWARD MARGERRISON

Office of Science and Engineering Laboratories, U.S. Food and Drug Administration (FDA), Director

Margerrison joined the FDA as the Office Director for the Office of Science and Engineering Laboratories. He is responsible for providing technical expertise and scientific guidance for policies relating to novel medical devices within the Center for Devices and Radiological Health. Margerisson has held many senior positions from biotech startups to leading biotech companies. He obtained his Ph.D. in Molecular Genetics from St. George's Hospital Medical School in London UK.



CHERYL LIU
Stryker Corporation,
Senior Principal Engineer

As the Senior Principal Engineer in Stryker Orthopaedics, Liu leads the deployment of advanced simulation applications throughout a product's lifecycle to improve patient care in the real world. Her close collaboration with experts from academia, industry and regulatory bodies serves to help advance and boost regulatory acceptance of simulation technology. An engineer par excellence, she earned her Ph.D. from the University of Notre Dame, U.S. and volunteers her time in the American Society of Mechanical Engineers and The Orthopaedic Research Society.

THE RACE IS ON

As competition heats up, medical device companies must develop devices faster than the competition while improving quality in a sustainable business model.

But with almost <u>2 million</u> medical devices saturating the market today, a challenging industry outlook and a demanding regulatory environment, how do companies gain the **speed and agility** needed to win the race?

This handbook has the answers.

Designed for serious champions, it will help you drive changes throughout your business so you can dig deep into simulation-driven strategies to:



Design and engineer high-performance devices faster



Run trials and gain approvals quicker



Manufacture devices and bring them to the market at speed with the highest quality assured

HOW TO BEGIN

Maximize your success in three easy steps.

1

Set your goals in the **vision statement**.

This helps you discover where you are in the race and identify any gaps to close.

2

Get digital platform tips and simulation-driven strategies to navigate challenges with agility.

3

Form an action plan guided by the questions in the review section. Strengthen your approach at each checkpoint.

LET'S START



CHALLENGE THE LIMITS

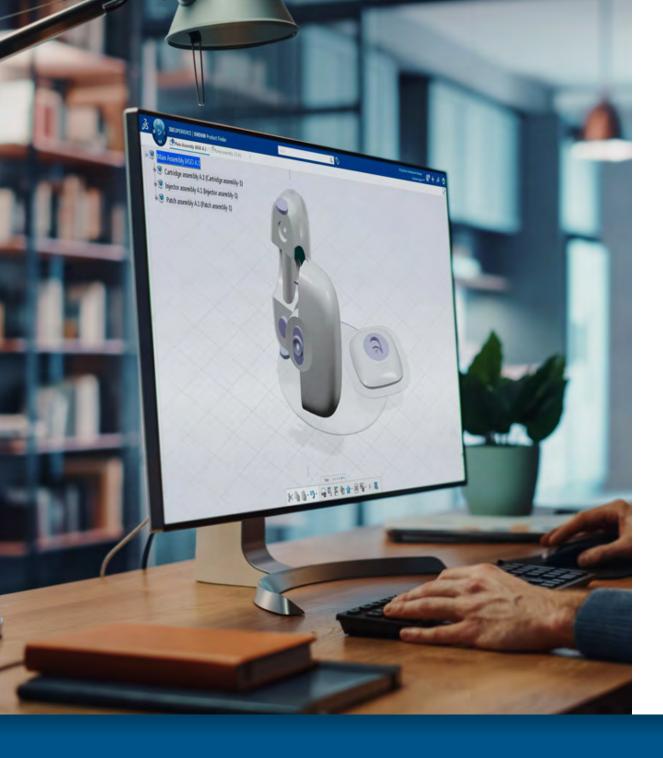
The medical devices industry is changing at an unprecedented pace. Whether pre- or post-pandemic, the industry drivers have pushed companies to shift from a conventional design-build-test method to a simulation-driven approach.

As a start, medical device companies must stem the **escalating cost and time** to develop new medical devices. On average, a new product development takes between three and five years and costs between \$30 and \$90 million. As devices get increasingly sophisticated and complex today, designing and developing them requires massive data to be shared in real time across stakeholders throughout the entire product lifecycle. Without a connected digital platform, design and development can be a laborious, lengthy and costly effort.

Beyond that, companies must tackle **rising product recalls** – often contributed to by design or manufacturing faults detected much later in the process. Since the beginning of 2022, more than <u>500 recalls</u> were recorded. An average of one company per year experienced a <u>10%</u> drop in share prices after a single major product recall. Unmitigated, these recalls can adversely affect a company's bottom line, damage its reputation as well as endanger its patient lives.

During the pandemic, the industry experienced a change in the way patients receive treatments and access healthcare. More patients are moving towards autonomous healthcare and **self-administered treatments**. For example, self-injection devices are on the rise and are tipped to reach <u>USD10.8 billion</u> by 2030 globally. This trend – predicted to continue post-pandemic – demands companies to step up and innovate faster for more effective, safer and more user-friendly devices that can seamlessly combine different technologies and drugs for patient use.





The pandemic also triggered **new working norms**, particularly in how medical devices are made and tested. When laboratories were inaccessible for testing during the pandemic, technology took on a major role to connect and facilitate remote working conditions and provide alternatives to bench, animal and human testing. The new working dynamics carry a heavy burden — to resolve business continuity challenges and ensure on-time and on-budget delivery of devices to patients amid disruptions.

The growing aging population, the prevalence of chronic diseases and the shifting focus towards early diagnosis and treatment are all driving the need for more radical designs in medical devices to solve unmet patient needs and help patients live better with these chronic diseases.

To top that, companies must navigate an increasingly **challenging regulatory environment**. Strict requirements necessitate an efficient documentation system that can competently track data through Device Master Record (DMR) and design history file (DHF) for faster approval submissions. Companies must be proficient in integrating data from multiple systems with varying complexities. Without a unified digital platform to act as the single source of truth and integrate data from siloed systems, companies will potentially lose the race

THE VIRTUAL TWIN EXPERIENCE ADVANTAGE

Dassault Systèmes is committed to turning these challenges into opportunities for success. The **virtual twin experience**, powered by the **3DEXPERIENCE®** platform holds the key to overcoming these challenges – thrusting companies to an unstoppable rise in the industry.

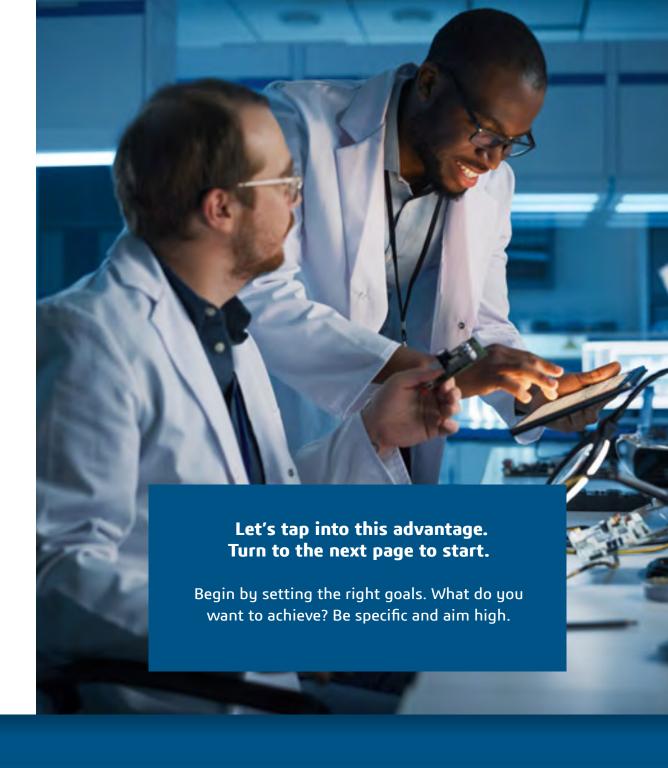
The distinct advantage lies in its **broad capabilities** to determine **performance**, **safety and quality of next-generation medical devices** with mechanical, electromagnetic and realistic human body **simulation**.

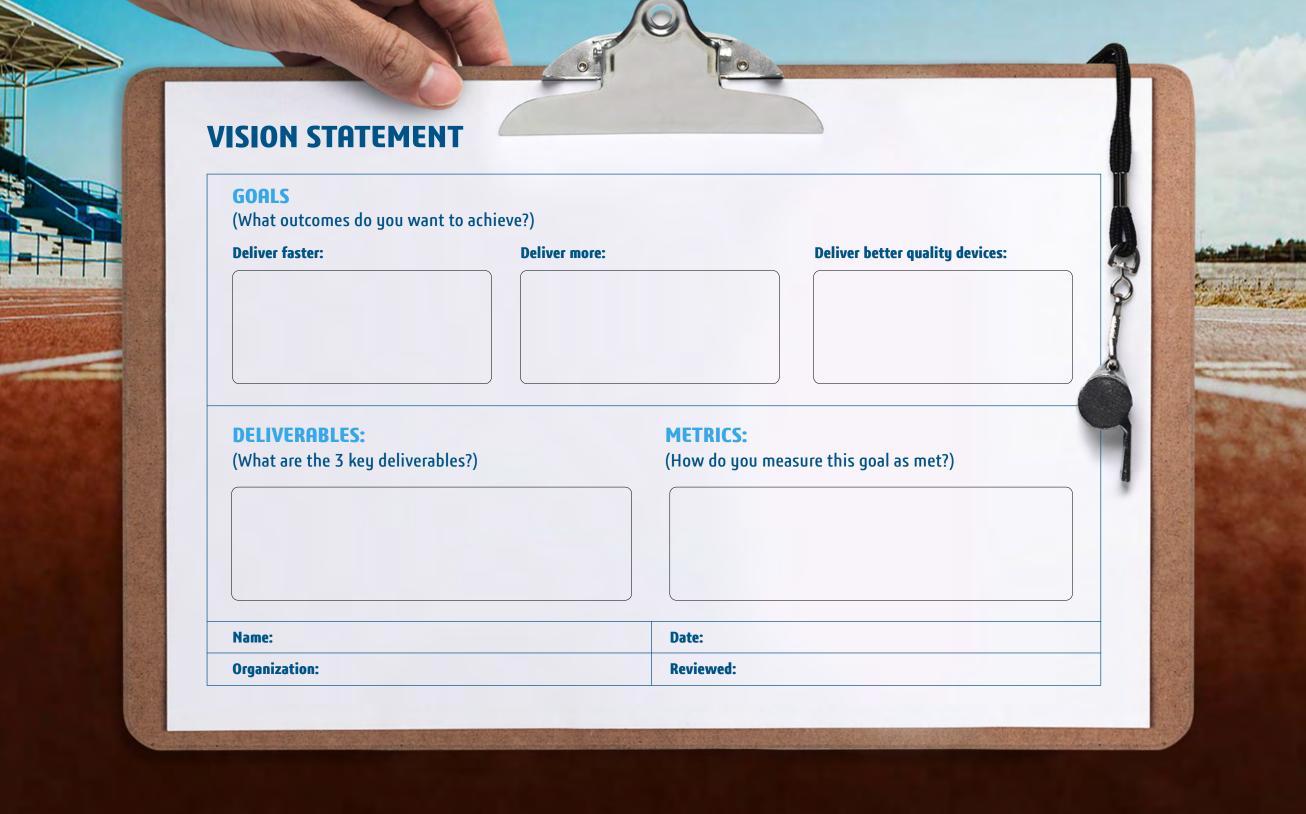
Unlike other solutions in the market, the **virtual twin experience** on the **3DEXPERIENCE** platform offers **end-to-end simulation** to help companies gain efficiency and cost and time savings at **each stage of the product lifecycle**. Dassault Systèmes' internal analysis of customer feedback found that companies were able to:

Shorten product development time by as many as two years

Significantly reduce the number of patients in clinical trials

Increase companies' capacity to innovate for better designs that will continuously improve patient experience







END-TO-END PLATFORM OPTIMIZATION

Imagine being able to predict the safety and efficacy of medical devices for your patients and develop superior devices at great speed and at the least cost to meet clinician demands. With the virtual twin experience powered by the **3DEXPERIENCE** platform, you can.

Karl D'Souza, SIMULIA Life Sciences & Healthcare Industry Process Director, confirms, "When we combine the ability to perform **realistic simulation** with the **3DEXPERIENCE** platform, we take the value of the solution to a completely different level."

A connected digital platform is especially vital to capitalizing on the global medical devices market growth, which is projected to grow to \$718.92 billion by 2029. As patients expect better transparency and companies move towards more outcome-based treatments, the platform becomes even more crucial for future collaboration, tracking and continuous improvement and **innovation**.



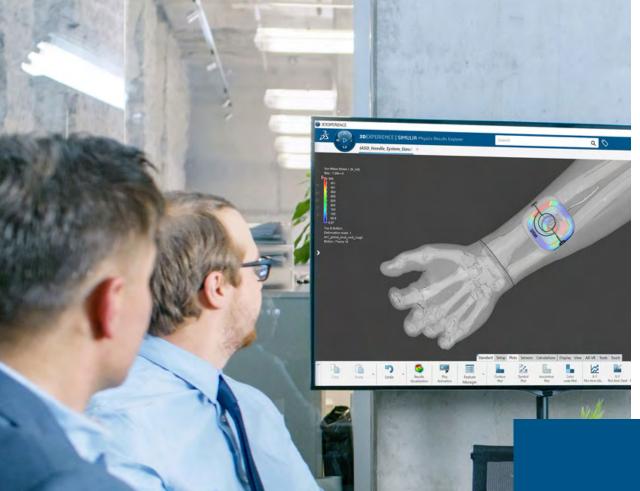
While medical devices are getting more sophisticated and complex – consisting of multiple connected systems and subsystems – John McCarthy, Life Science & Healthcare Industry, Business Strategy Senior Director reaffirms that the **3DEXPERIENCE** platform can manage these complex devices with agility. Here, companies are empowered to address unmet medical needs by connecting multiple engineering and scientific disciplines to collaborate and innovate by leveraging **data, models and know-how** across the product lifecycle. The platform connects disciplines holistically for effective **collaboration, design and systems architecture** by simplifying complex inter-related subsystems via a model-based systems engineering approach to deliver better systems design, verification and validation.

McCarthy stresses,

We can now **digitally connect end-to-end** across the product lifecycle – from ideation to manufacturing – to **democratize simulation** to stakeholders such as CAD designers, systems engineers and manufacturing collaborators. This is crucial to **shorten development time, get more iterations** through for designs and assess where the problems are going to be early in the process."



"For example," elaborates McCarthy, "a CAD designer needs a particular simulation, which takes about 20 minutes to run. Instead of waiting 10 days for that one designated person, with 100 other tasks on his to-do list, to find the time to run the simulation and share the results, the designer can perform the simulation on his own and uncover any faults early within 20 minutes. Now, here's the compounded value: As devices get more complex, there are more design iterations across more people and a 10-day turnaround time increases exponentially into time lost. So democratization of simulation can add up to massive time savings."



The platform also benefits device **manufacturing**. Claire Biot, Life Sciences and Healthcare Industry, Vice President explains, "The **3DEXPERIENCE** platform improves the technology transfer time by 40% and helps companies gain 25% in production throughput as companies optimize their manufacturing operations."

D'Souza adds, "As different stakeholders – from marketing, designers to even third parties such as part suppliers – **collaborate** on a common platform throughout the entire process, this results in maximum use of the company's experience, talent and knowledge, which reduces time to market and risks of product failure."



RACE better with the **3D**EXPERIENCE platform. Get ready to **r**aise productivity, **a**ccelerate innovation, **c**ollaborate in real time and **e**ngage all stakeholders better.

Discover the <u>collaborative</u> engineering management.



The experts share more platform-driven values summarized in five key areas as follows:

Key transformation areas	How it works	User values
○:: Innovation >: ond advancements	Bridge the gap between the virtual world and real world needs to amplify design innovation for more patient-centric solutions	Design, develop and test innovative devices virtually to meet patient needs – reducing siloed operations and the need for expensive prototyping and lengthy trials
్ష్మన్ర్మే Productivity ష్వే and performance	Support multiple simulation methods across multiple engineering techniques, which drive efficient device development and increase device performance	Produce safe, effective and quality products faster and at a lower cost that meet patient, healthcare worker and regulatory needs
Collaborative 是登显 environment	Connect multiple stakeholders in real time, incorporate complex systems and multiple components used in a device on a single platform to speed up collaboration, testing and approvals	Offer alternatives to bench testing and animal and human testing to lower cost, shorten processes, afford better transparency and boost efficient collaboration to value-add the entire value chain
Data-driven workflow	Acts as a central repository to offer collective insights on data, integrate data from multiple systems to offer a single source of truth and streamline processes	Improve device designs through data-driven insights, provide accurate DHF and DMR data for faster regulatory filing, and enhance risk assessment
Digital continuity in manufacturing	Understand assembly process and components needed, address manufacturing issues early in the design stage and democratize modeling and simulation beyond the specialist to resolve basic issues early	Avoid sending poor designs downstream in the development cycle, minimize product recalls, cut down redesigning costs and preserve a healthy bottom line with end-to-end visibility



ACCELERATE WITH END-TO-END SIMULATION



Why is end-to-end simulation important?

Biot explains, "When you want to bring a new device into the market, you need to design and engineer it, run clinical trials and manufacture it. On average, it will cost \$30 to \$90 million and takes up to five years to develop new devices. **Simulation can shorten this time and reduce cost significantly** by **connecting the lifecycle stages** from end to end.

Simulation on the **3DEXPERIENCE** platform opens up collaborative spaces, generates multiple design options virtually, replaces physical trials and helps companies manufacture devices in the most sustainable way. This also means getting safe, effective, quality devices more quickly and affordably to the patients."

D'Souza highlights further how simulation can alleviate medical device safety concerns. He says, "Each year, more than 95% of devices are released into the market through the 510(k) or premarket notification. These devices are not mandated by the FDA for premarket approval (PMA) or the trial route, which heightens the safety and efficacy concerns of the medical devices – simply because they are not tested in humans before. As such, simulation and the virtual human modeling in particular, are of central value to ensure that safety is prioritized throughout the development process from end to end."

By identifying critical breakthrough areas and measuring performance at each lifecycle stage, simulation can help companies focus on improving processes and enhancing efficiency to bring safe and effective medical devices to the market faster.



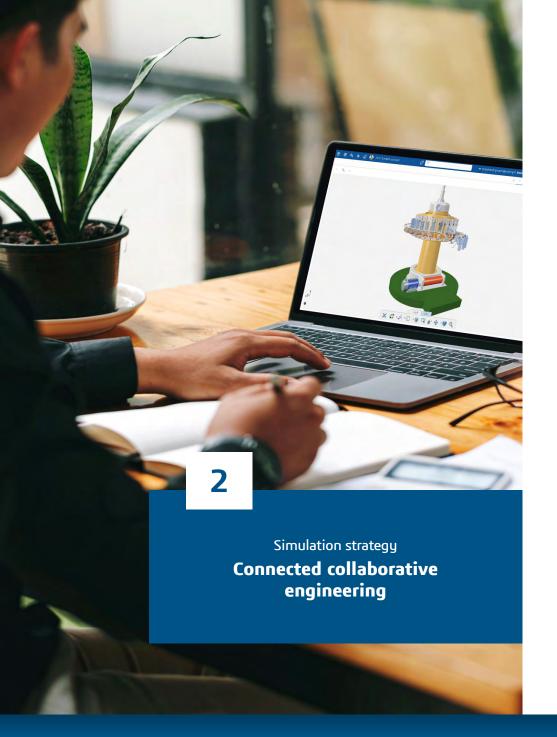
Strategies for simulation across the medical device lifecycle include:

Process improvements

- Leverage powerful mechanical, electromagnetic and realistic human body simulation capabilities to reduce physical bench testing and drive device performance
- Connect multiple engineering disciplines to eliminate the late discovery of design issues, help expand capacity and speed up time-to-market
- Explore multiple design concepts and test, validate and verify ideas and performance across all physics domains (structural, fluidic, electromagnetic, thermal and more) to meet unmet patient needs
- Simulate implant designs (e.g. orthopedic and dental) using patients' quality
 of life metrics to optimize implant performance and maximize
 personalization benefits

Tools to increase efficiency

- Reduce physical bench testing by simulating <u>Device Mechanical</u>
 <u>Engineering performance</u>
- Create connected devices with antennas or sophisticated imaging devices such as MRIs with <u>Device Electromagnetics Performance</u>
- Optimize device behavior and performance in humans by simulating devices in realistic human models, including heart, tissue, lung and knees



Process improvements

- Share design data with stakeholders, manage projects, assign tasks and collaborate efficiently to increase productivity
- Offer stakeholders full visibility of the medical device to:
 - Build a collaborative engineering model
 - Manage seamless bill of material changes
 - Track issues and enhance understanding of device performance effectively
- Ensure full traceability and target requirements are met on time and on budget
- Enable optimization of the use of standard components by identifying similar parts in the company catalog, grouping them as clusters and proposing alternatives
- Classify parts under the right category and choose the parts to be recommended based on technological, vendor or price information
- Reuse parts, 2D/3D designs and related documentation to realize savings across the company
- Negotiate for better price on volume

Tools to increase efficiency

- Accelerate cross-team collaboration to reduce production and sourcing issues through flexible data visualization and efficient product engineering definition with Collaborative Engineering Management
- With <u>Standard Component Management</u>, deploy an efficient and cost-effective standardization and sourcing process that increases product quality and is aligned with business policy

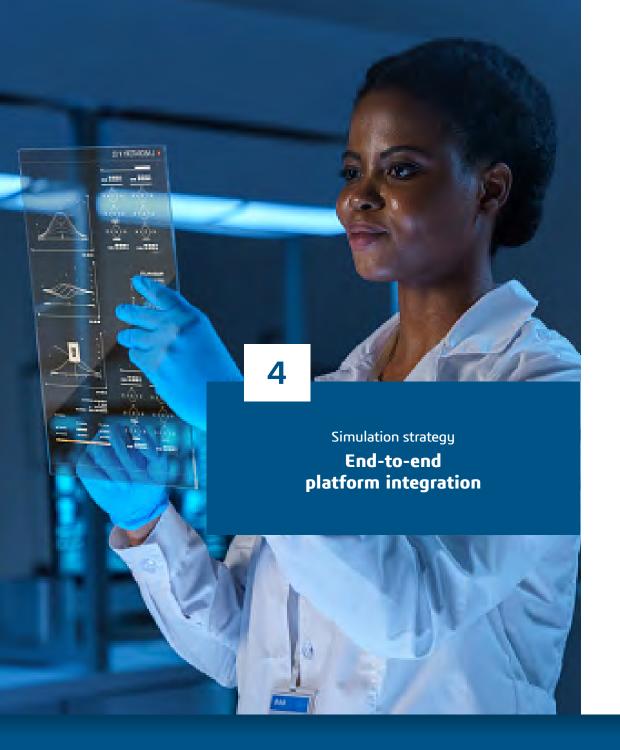


Process improvements

- Incorporate the understanding of assembly processes and identify manufacturing issues early in the design stage instead of during handover to manufacturing to:
 - Ensure devices are manufactured without quality issues and function at optimal performance
 - Reduce manufacturing scrap
 - Eliminate costly returns to the design stage late in the game
 - Shorten the go-to-market time and generate revenue faster
- Offer precise planning and forecasting to optimize manufacturing processes removing bottlenecks and increasing throughput for faster time-to-market
- Enhance speed in assembly, packaging and sterilization, and ensure quality in compliance with strict ISO-certified and regulated processes and facilities

Tools to increase efficiency

- Digitalize processes and simulate production to meet global demands with <u>Manufacturing Process Engineering</u> to:
 - Predict and avoid costly production problems
 - Validate the assembly before manufacturing and avoid expensive prototyping
 - Shorten the learning curve for production workers by up to 50%



Process improvements

- Connect multiple simulation capabilities across multiple engineering disciplines, foster unique digital collaboration and automation to facilitate quicker design iterations, shorter lead times and better designs while accelerating product innovation to new levels
- Gather data insights on the volatile market to strategize new product launches for better marketability and profitability
- Provide accurate evidence to support regulatory filing and FDA approvals

Tools to increase efficiency

With the **3DEXPERIENCE** platform, medical device companies can experience life-like, multi-scale and multi-physics models and virtual twin experiences – bridging the gap between the experimental and real worlds, **all the way through the innovation cycle from design, development, clinical trials and manufacturing.**



OUTPACE THE COMPETITION

Together with global industry leaders, Dassault Systèmes brings safe and highly advanced medical devices **faster** to the market to **improve patient experience** around the world. Be inspired by our customer success stories:



Mevion Medical Systems

Mevion, a leading medical device company provider of proton therapy treatments for cancer patients, aimed to enhance beam quality for effective and safe laser treatment on cancer cells. Dassault Systèmes' Opera for finite element analysis enabled low frequency electromagnetic (EM), electromechanical and multiphysics solver to simulate an advanced interaction of various EM fields leading to tumors being destroyed with a higher precision, safer and more effective method.



Novo Nordisk

Novo Nordisk's goal to design efficient insulin-delivery pens focused on understanding the time dependent viscous behavior of thermoplastic materials in snap-fit loads during manufacturing and patient use. Dassault Systèmes' SIMULIA Abaqus FEA helped Novo Nordisk model and simulate these diverse material characteristics, analyzed design parameters and refined models to suit patient needs, thus **delivering efficient and high-performance devices** for a **better patient experience**.



Flow Robotics

To alleviate the burden of bioanalysts in hospitals and labs, Flow Robotics created robots to automate physically demanding and repetitive manual pipetting tasks with greater accuracy and minimal errors. The **3DEXPERIENCE** platform connected workflows and made them more efficient to support faster growth and smarter innovation. Flow Robotics gained better visibility across the board and leveraged crucial data to accelerate product development.



GE Healthcare

With over 54,000 employees worldwide, global healthcare leader GE Healthcare used the simulation capabilities of Dassault Systèmes' SOLIDWORKS in **innovative design** to help the **product development cycle move faster** for its anesthesia drug delivery. With SOLIDWORKS, GE Healthcare simulated multiple jobs and compared performance criteria in different failure modes to **validate design**. This helped GE make better working products faster.

Dassault Systèmes' continuous collaboration with regulatory bodies and established partners in the field has helped shorten go-to-market time by refining medical device performance, creating value for patients and navigating quality challenges faster.





Cheryl Liu Stryker Corporation

"At Stryker Joint Replacement, we have been using Abaqus since 2012. The two main areas accelerating the use of Abaqus are the biomechanics and manufacturing process simulations enabling virtual iterations of our designs and processes under realistic conditions. By simulating product performance and process efficiency early in the lifecycle of a product, especially in the concept development stage, we can analyze virtually how a product will be manufactured and tested, and how it will perform clinically prior to making the decision to initiate a project. This helped us gain more confidence in the concept and reduce business risks associated with investing in a new product development project."



Edward MargerrisonU.S. Food and Drug Administration (FDA)

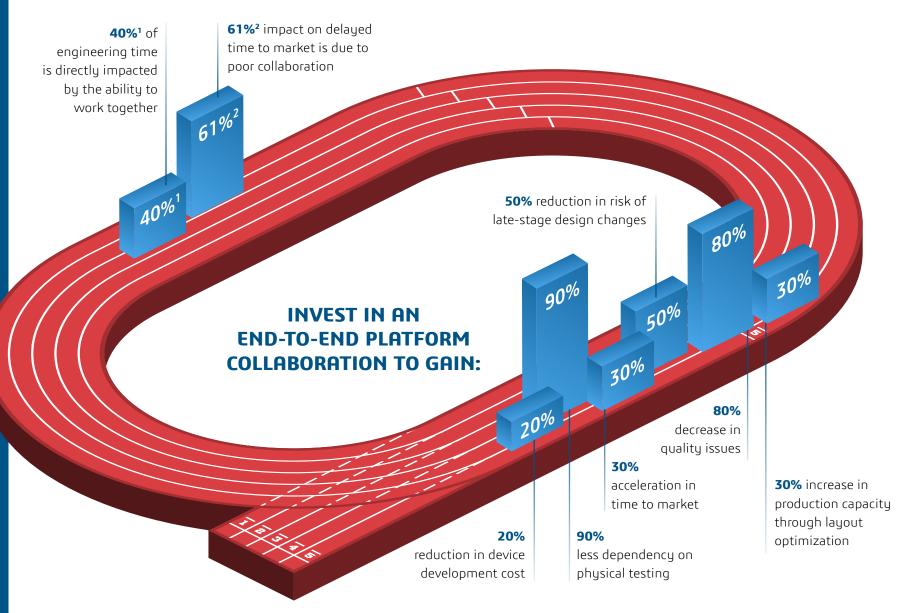
"For regulatory purposes, a standardized method or streamlined approach across the medical device community is best to boost efficiency in device assessment and evaluation methods. That's why a standard guide on *in silico* clinical trials will be important, not because everybody is going to rush around and model mitral valve regurgitation, but it's to provide a pathway to developing models that can be more easily accepted at the regulatory phase."

Experts and customers alike agreed that end-to-end simulation on a collaborative platform is the way forward for medical device development to win the speed and quality race. Here's why.

WHY MEDICAL DEVICE COMPANIES MUST ADOPT A PLATFORM-DRIVEN SIMULATION APPROACH

(Source: Dassault Systèmes internal customer feedback analysis on Engineered to Cure and Made to Cure solutions)

DID YOU KNOW?





UNLOCK A NEW ERA OF HEALTHCARE

Simulation transforms **clinical trials** to bring the medical devices industry to the next level.

With *in silico* trials, **trial time and cost can be significantly reduced** as companies move away from *in vivo* and *in vitro* testing, which often raises ethical and safety concerns too.

At Dassault Systèmes, efforts are already underway to conduct more *in silico* trials alongside the FDA through two important projects:



Simulation of real-life **human anatomy** for mitral valve regurgitation trials of a repair device



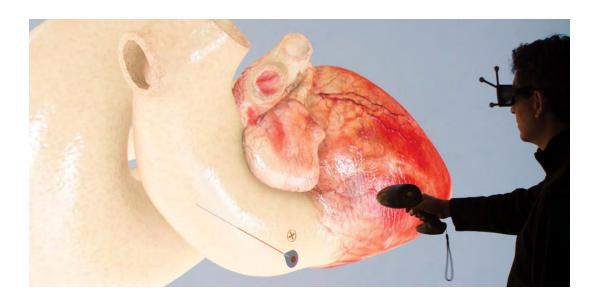
Data-driven simulation for a synthetic control arm

"The aim is to innovate and perform efficiently in *in silico* trials, allowing **patients to access devices faster** and avoid being the experimental subjects in the development of new devices," says Biot.

Expanding on simulation's scope of work in clinical trials, D'Souza adds, "Simulation-based clinical trials can create a **population of patients virtually**. This is instrumental when we want to test devices on certain demographics and conditions that are hard to find in real

world representation. Simulation's value lies in its ability to simulate virtual models of any kind of disease, demographic requirements and conditions with high variability. This greatly contributes to gaining accurate results for device efficacy."

Additionally, these virtual patients can be enriched with more sophisticated and unique behavior, such as race, gender, age, and genomic profile to allow the **development of smarter devices that works** harmoniously with the body.





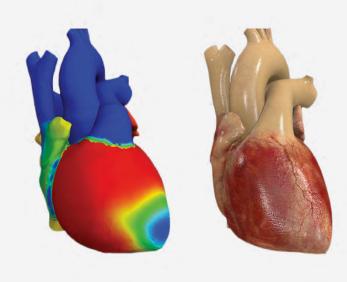
"By virtue of simulating on the highly collaborative **3DEXPERIENCE** platform, the FDA and other regulatory bodies can be involved in the very early stages of device design. Incorporating their insights, suggestions and guidance early can increase the probability of approval," adds D'Souza.

The FDA's recent issuance of guidance detailing a risk-based framework on how to assess the credibility of simulation models for approval submissions highlights further the FDA's growing positivity in accepting simulation-driven in silico trials as trial evidence. With this progress, companies can expect shorter approval processes, lower trial costs and minimal failure rates in the future.

Checkpoint 3:

The Living Heart Project is a groundbreaking project leveraging the virtual twin to revolutionize cardiovascular science through realistic simulation. In partnership with the United States Food and Drug Administration (FDA), the project continues to spur medical device innovations for the future and has since inspired similar projects for the lungs, brain and knees.

Discover the Living Heart Project

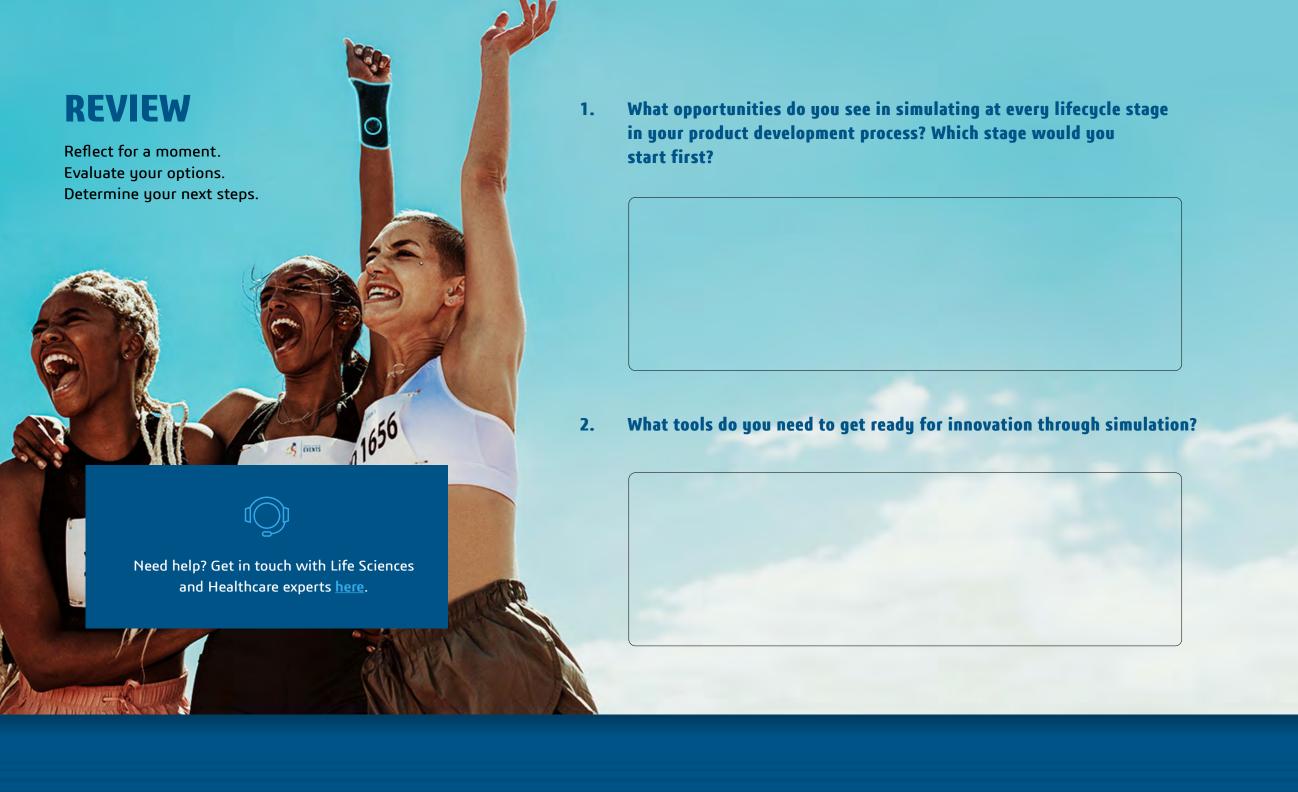




If you want to win the race against your competition, get your products ahead in the market to meet patient-specific needs, and be superior in quality, safety and efficacy, then simulation is the only way forward.

- John McCarthy
Life Science & Healthcare Industry,
Business Strategy Senior Director

Track your simulation-driven approach for success.



Making sure medical devices work safely and effectively in the complex human body amid rising costs and safety concerns continues to be the biggest challenge for medical device companies. But as elaborated in this handbook, end-to-end simulation makes it possible for companies to rise above these challenges and forge unstoppable success into the future.

D'Souza, on recapping simulation's value, says, "Whether it's dental, orthopedic, cardiovascular or other complex implants in the future, simulation helps us understand better how these will work in the human body so we can **design comfort, optimize safety** and **increase efficacy** to better **personalize treatments** and **improve the patient's quality of life**."

McCarthy emphasizes, "We run fewer design iterations faster and **increase the speed** of devices to the market when we **democratize** simulation on a **highly collaborative environment**, which shortens time, decreases waste, and lowers cost."

Perhaps the biggest advantage of the simulation-driven approach across the product lifecycle is the ability to simulate and innovate from a **single source of truth**.





To this, Biot concludes by drawing a fascinating parallel to an airplane story, "When airplanes were made 40 years ago, you had to hire mathematicians who were good in airplane geometry because they needed to look at the plan and visualize the 3D model in their minds.

So, when it came to collaboration, it was difficult because everyone would picture the model in their heads, but nobody could see another person's thoughts.

However, when the virtual twin experience was made available, everyone sees the **same representation** of the model. This **prevented many mistakes** from happening, **accelerated development** and **extended progress into the entire lifecycle**. This is what we want for the medical device industry too. To **achieve high quality standards** and **collaborate to enhance** and **optimize medical device** in the shortest time possible."

Want to learn more? Get the full Industry Solution Experiences here.

REFERENCES

- 1 Cost of Poor Collaboration in Engineering
- 2 Cost of Poor Collaboration in Engineering

Checkpoint 4:

Go for the win. Remember to:

- 1. Adopt simulation-driven strategies and platform tools for efficient processes.
- 2. Make the changes needed to achieve your goals using the vision statement and review section as a guide.
- 3. Revisit this handbook anytime a refresher is required.





Inceptra supports engineering and manufacturing organizations with best-in-class solutions to digitally design, simulate, produce, and manage their products and processes, enabling enhanced innovation and productivity.

As the largest Platinum partner in North America, Inceptra is dedicated to Dassault Systèmes' product development software portfolio, complementary solutions, and related services, including training, implementation, integration, support, consulting, and automation services. For more information, please visit Inceptra.com.

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Our **3D**EXPERIENCE® platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3DEXPERIENCE** Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating 'virtual experience twins' of the real world with our **3DEXPERIENCE** platform and applications, our customers push the boundaries of innovation, learning and production.





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