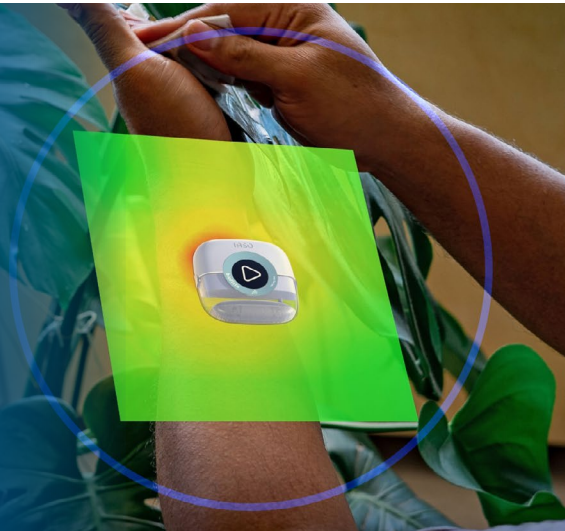


VIRTUAL TESTING OF MEDICAL DEVICES

Get Compliance-Ready



Design Verification on a Single Source of Truth

Successful medical device innovation depends on feasibility, reliability, manufacturability, and product safety. Traditional development remains siloed and heavily reliant on physical testing, which is costly and slow. Virtual testing transforms the development process. High-fidelity simulation enables faster design evaluation while reducing time, cost, and effort. MedTech companies are increasingly recognizing its value and starting to realize its full potential.

CHALLENGE

Physical Prototyping Paradigm Limits Innovation and Increases Costs

Building and testing physical prototypes for verification not only restricts flexible development and slows down design processes—it also increases cost for every iteration. Repeated testing makes it difficult to predict the overall budget for product development.

BENEFITS

- Reliable and validated Virtual Test Lab powered by world-class simulation technology
- Scale-up design verification process by* **10x**
- Reduce physical prototypes **up to* 50%—lowering testing and developmental cost**—which can lead medical device manufacturers to optimize verification/validation processes with SIMULIA

*Based on Dassault Systèmes customer project estimation.

Regulatory Compliance of Virtual Testing

How can safety, quality, integrity, and traceability of virtual tests be demonstrated to regulatory bodies?

- Guided process for FDA-recognized ASME V&V40 standard to demonstrate credibility of computer simulations
- GxP-ready cloud platform with ISO 9001 certified quality management system

Empower Designers to Take Decisions Faster

Traditional simulation technologies require specialized expertise that is usually not available to design engineers, limiting the impact of virtual testing on design decisions.

- Democratized high-fidelity simulations accessible to design engineers
- Standardized virtual test templates for compliance by design
- Faster exploration of multiple ideas offers deeper insights and better products validation processes

Challenge:

A global medical device manufacturer worked with Dassault Systèmes to accelerate the simulation verification of a syringe design.

Designers can now:

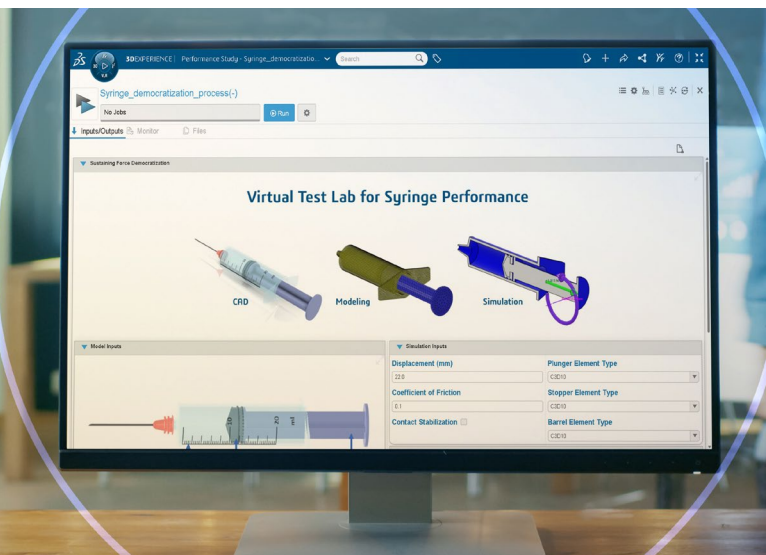
- Validate designs virtually
- Assess new concepts quickly
- Modify designs in real time
- View dynamic results through an intuitive interactive dashboard

Results:

The customer now develops more efficient, innovative, reliable, and compliant products in less time and at lower costs.

Customer Story

After a proof of concept, a “Virtual Test Lab” was created for the company. It provides automated simulation templates that enable designers to assess key design challenges independently.



“Democratization” of simulation.

By automating complex, standardized, and high-usage simulation workflows, combined with an easy-to-use interface, we make simulation accessible to all users.

Get Compliance-Ready with High-Fidelity Virtual Testing

Empowering medical device developers to evaluate nearly every aspect of product performance through highfidelity computer simulation can help to reduce the reliance on time-consuming and expensive traditional bench testing. With the ASME V&V40 standard, the US FDA has provided guidance on how to assess computer simulation results for medical device regulatory submissions. The combination of democratized computer simulation workflows with an integrated V&V40 process delivers unsurpassed efficiency gains for the verification and validation of medical devices.

Why Choose SIMULIA?

- Designer-centric guided virtual test lab
- Proven world-class simulation technology
- Integrated CAD modelling and physics simulation
- Comprehensive multi-physics simulation capabilities
- FDA-recognized V&V40 process to demonstrate simulation credibility
- GxP-ready cloud for security, scalability, and easy deployment
- Compliant with FDA (21 CFR Part 11), EMA (EU Annex 11), and ISO 9001

Find out more

See how medical device designers can leverage the [SIMULIA simulation portfolio](#).

www.3ds.com/products/simulia/life-sciences-healthcare

Join the SIMULIA Community to learn more about the [Virtual Test Lab](#).



Dassault Systèmes is a catalyst for human progress. Since 1981, the company has pioneered virtual worlds to improve real life for consumers, patients and citizens.

With Dassault Systèmes' 3DEXPERIENCE platform, 370,000 customers of all sizes, in all industries, can collaborate, imagine and create sustainable innovations that drive meaningful impact.

For more information, visit: www.3ds.com

**Virtual Worlds
for Real Life**

