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DIGITAL INDUSTRIES SOFTWARE

The role of simulation in medical device development

Why digital transformation is key to mastering today's challenges and unleashing innovation

Trends that are driving the need for digitalization in medical devices

- Increased demand for devices
- Personalized treatments
- Connected devices
- Regulatory compliance & validation
- Generating digital evidence

Challenges facing medical device designers

- Multi-disciplinary work & need for strong collaboration
- Strict timelines
- Strong competition
- Providing quality evidence for product safety
- Collecting & organizing compliance data

How simulation shapes medical device innovation

Simulation refers to a physics-based digital twin of a device, serving as the cornerstone of product development. It helps ensure:

- ☑ greater insight
- ☑ improved efficiency
- ☑ reduced development cycle time
- ☑ increased market agility

Simulation is an invaluable tool that can be used at every stage of the product lifecycle

Early device development
- Select the best performing design
- Lower development costs

Regulatory approval
- Reduce the size/ scope of clinical trials
- Validate credible simulation results

Manufacturing
- Guide production decisions
- Evaluate late-stage design impacts

Post-market surveillance
- Identify root cause of malfunctions
- Select design changes to address issues

Digital evidence generation via simulation

The process of using simulation to generate engineering information establishes product performance, an effort supported by the FDA and regulatory agencies worldwide.

> CM&S (computational modeling and simulation) of medical devices can streamline development and reduce burdens associated with premarket device evaluation. It can also reveal important information not available from traditional in vivo or in vitro assessments, such as serious and unexpected adverse events that are undetectable within a study sample but occur frequently enough within the intended population to be of concern.
>
> -Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submission, FDA, 2023

Key medical device application areas for simulation

Orthopedics and personalized implants
- Additive manufacturing
- Biomechanics
- Lattice structures

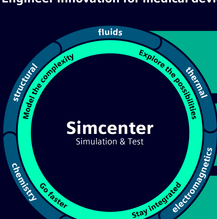
Laboratory and diagnostic equipment
- Microfluidic devices
- MRI and CT scanners

Cardiovascular and neurological
- Modeling blood flow
- Effects of stents and heart valves

Surgical equipment and medical robotics
- Sterilization
- LED lighting

Prosthetics and exoskeletons
- Create customized, affordable products
- Test hydraulics

Simcenter portfolio
Engineer innovation for medical device performance



Design analysis and functional performance
Fluid flow, motion, noise/vibration, durability, SH-HW integration

Variability and robustness
Impact of variability from multiple interacting sources

Information and process management
Maintain results records and track activity for reporting

To learn more, visit

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