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Realistic Simulation for Medical Device Developers

Introduction

Medical device developers use realistic simulation solutions from SIMULIA to accelerate the overall product innovation process, reducing development costs, and improving patient safety and product quality.

In addition, SIMULIA provides medical device companies with the ability to more efficiently evaluate design alternatives, accelerate long-term stress life testing to predict product reliability, collaborate on projects and leverage computing resources for more efficient design analysis.

1. What is SIMULIA and how can realistic simulation be used by medical device developers?
2. To a medical device developer, what are the benefits of using this platform? / How will this platform impact their organization?
3. How can this platform be applied to the healthcare industry at large?
4. How will the implementation of realistic simulation help the industry evolve and break down silos within healthcare?
5. What has been the FDA's interest in realistic simulation and how do you see it affecting the healthcare industry and medical device developers?
6. What does the future hold for this platform and how do you see this technology influencing the industry in 5 years?

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What is SIMULIA and how can realistic simulation be used by medical device developers?

Historically, simulation has not played as critical of a role in Life Sciences as it has in more traditional engineering industries like Automotive or Aerospace.

The product development process and innovation cycle for medical devices has been different, characterized by development of an effective and safe device; with less regard for optimal performance, lowest cost etc.

The testing and validation process led by medical device manufacturers is traditionally validated through animal studies and subsequently human clinical trials depending upon the product type, application and use. However, there is a move to do more testing virtually through the use of computational modeling and simulation. Moreover, the simulation of the human environment the devices would interact with is considerably more difficult than that of metal, plastic or ceramic components.

Human tissue response is complex, difficult to measure in the lab and not easily simulated with simplified models. The physical conditions that replicate real world use of devices are often not well understood. As a result, animals and ultimately humans become the proving ground of a design, dramatically limiting the cycles for innovation. The SIMULIA product suite now contains a wide variety of material models, procedures and load types to simulate the human body itself, medical and surgical equipment , and the manner in which the equipment is used. Today, Abaqus is widely used to simulate implanted cardiovascular devices (stents, artificial heart valves, pacemakers), orthopedics (artificial knees, hips, spine), brain injury due to head impact , dental implants, tissue modeling mechanics of feet and hands, and pumps and portable devices for blood monitoring, among other applications. Abaqus results are used in PMA and 510-K submissions required by the US FDA and have similarly been used to obtain CE mark approval in Europe. In addition, as part of the 3DEXPERIENCE product innovation platform, SIMULIA can be used in a global collaborative framework allowing distributive teams to collaborate together around the same set of common data for more efficient design, testing and evaluation of new ideas. Engineering design and test data can be linked to the DHF and DMR and, as part of the ENOVIA and License to Cure for Medical Device solutions.

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To a medical device developer, what are the benefits of using this platform? How will this platform impact their organization?

In a cost constrained, highly regulated, competitive market, medical device companies are faced with the challenges of delivering innovative products that improve patient outcome at lower costs.

With globalization of medical device companies, disparate development teams, use of third party sub-contract manufacturing companies, silo based systems, paper based record, medical device companies have to innovate the way they innovate, to streamline and improve upon the product development life cycle of a product, thereby facilitating the capability to accelerate product innovation, reduce costs and improve quality and patient safety.

Companies that fail to incorporate digital continuity within the product development process – which includes links to engineering, quality and regulatory processes/approvals/reporting – throughout the lifecycle of the product increase the threat of compliance risk, delays to market, cost overruns, increased parts scrap due to rework, product recalls, and increased risks of 483 warning letters citations. Many compliance risks are due to traceability gaps coming from legacy paper-based systems, data stored in multiple silo based locations throughout the organization, and no single unified change management system. Engineering , quality and regulatory collaboration is key to developing high quality products and must work closely together throughout the product development lifecycle.

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How can realistic simulation be applied to the healthcare industry at large?

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The 3DEXPERIENCE product innovation platform is exactly that – a platform that can help accelerate the product innovation lifecycle from concept innovation to design, development, V&V, clinical, regulatory, launch, post market launch assessment and end-of-life, by linking with other applications of any kind and connecting various stake holders like product marketing, R&D, clinical, regulatory, quality, sales, manufacturing across the globe to the same set of common data. But even more importantly, it can help manufacturers connect with patients, providers, and their product use in the field as well.

Netvibes Social + Enterprise Dashboard Intelligence helps enterprises monitor and manage everything in real-time, providing personalized dashboards for better, more informed faster decision-making. Now you can get a status update and understand everything that matters across all your internal systems anywhere, anytime, on any device.

How will the implementation of realistic simulation help the industry evolve and break down silos within healthcare?

Realistic simulation has massive potential to dramatically transform healthcare, with benefits ranging from:

- ✓ Educating patients.
- ✓ Training physicians.
- ✓ Enabling new innovations in devices and procedures.
- ✓ Driving down the time and cost for FDA approvals.

But even further, we believe that realistic simulation will play an unprecedented role in the emergence of personalized medicine.

It has the potential to precisely develop personalized therapies and unique treatments – that offer cures and remedies to ailments never before thought possible.

The case of The Living Heart Project

In the case of The Living Heart Project, we are creating realistic, electro-mechanical human heart models to re-construct a full beating heart so that one day, post-diagnosis, a clinician or surgeon can reliably determine the best course of treatment possible unique to that patient's particular situation. The Living Heart Model also has applications pre-surgical patient engagement reviewing with the patient the condition of their heart and the surgical therapeutic intervention that will take place. Additional applications include selecting the optimal size implant (stent) for the patient, pre-surgical planning, education and other applications.

The Living Heart model is the first of its kind, showing what is possible and we are now progressing toward our vision of a digital representation of the human body. See link to Living Heart Project video, and learn more about The Living Heart project here.

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What has been the FDA's interest in realistic simulation and how do you see it affecting the healthcare industry and medical device developers?

As life sciences engineers embrace simulation, they are achieving increasingly accurate levels of precision when evaluating device function, including the ability to evaluate aspects of device performance not possible with bench tests alone.

As a result, the FDA's Center for Device and Radiological Health (CDRH) is seeing a growing number of submissions for medical devices that include a simulation-data component.

The CDRH is responsible for regulating firms that manufacture, repackage, re-label, medical devices sold in the U.S. The submissions for these therapeutic devices typically contain data from four types of evaluation models—animal, bench, computational, and human—to demonstrate a reasonable assurance of safety and effectiveness. When a company submits simulation metrics that supplement bench testing, this can help promote approval by demonstrating both the integrity of the proposed device and the required realistic device failure analysis. As the ultimate safety-and-effectiveness regulatory body between medical device manufacturers and patients, the FDA recognizes the value of such advancing technologies—and its own need to stay abreast of them—and has now begun actively encouraging the use of simulation in device evaluation.

Snippet from article:

https://www.mdtmag.com/article/2013/04/simulation-now-recognized-fda-essential-medical-device-evaluation

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What does the future hold for this platform and how do you see this technology influencing the industry in 5 years?

The application of computational simulation modeling will have a diverse impact within the:

(a) Development of medical devices, combination products, pharmaceutical drugs.

(b) Accelerating clinical trials.

(c) Personalized medicine.

(d) Complete virtual human body interactions, in being able to identify critical functional and relational aspect of the human body and in assessing how the human body will respond to certain forms of therapy.

(e) Teaching and (e) patient engagement from diagnosis to preventative care.

Dassault Systèmes is committed to serving the Life Sciences industry and has a long history of transforming industries through partnership and consistent investment in both developing and acquiring technologies that enable the right solutions unlike any other provider. With the addition of Accelrys in 2014, we have already become a leading provider for Life Sciences.

We will continue to expand our solution portfolio further, partnering with leading biotech, pharmaceutical manufacturers and healthcare providers to go even deeper in the life sciences in specialty areas like cancer and other break-through fields where research and cures are so desperately needed. So the future is bright, for Life Sciences, the healthcare field, and for patients around the world.

Dassault Systèmes, the 3DEXPERIENCE Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 210, 000 customers of all sizes, in all industries, in more than 140 countries. For more information, visit www.3ds.com.

Watch Dr. Steve Levine discuss 3D Design and Collaborative Platforms to Support Digital Health at Generis' American Medical Device Summit 2016.

Check out the video below!

DR. STEVE LEVINE

Senior Director,
Product Strategy /
Executive Director,
Living Heart Project

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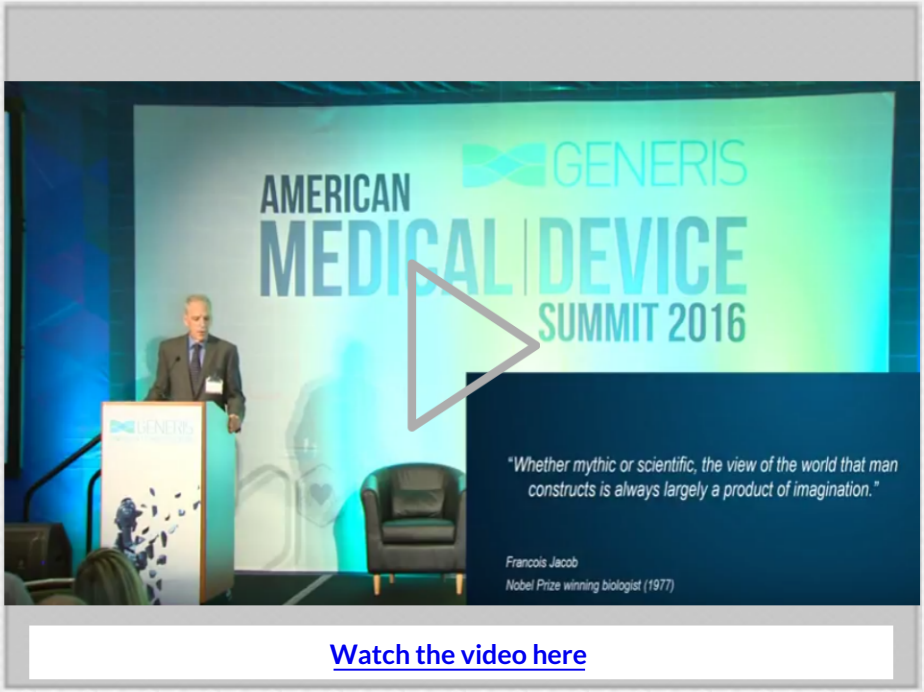

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