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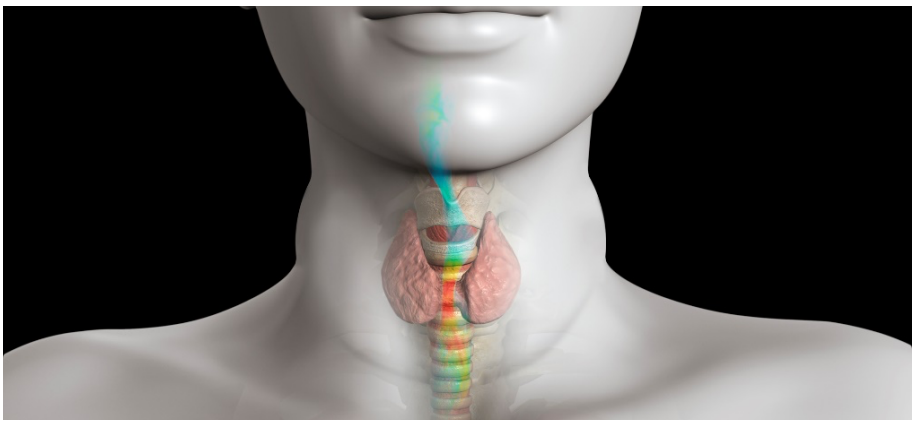
# Design Excellence

## Conquering product and regulatory complexity through collaborative design

The era of “smart” technology has gradually permeated the medical device industry. Patient and provider needs are evolving, regulatory scrutiny is growing, and exciting technology advancements are simultaneously heating up competition and making products more challenging to validate in terms of safety and efficacy. The result is a level of complexity that makes it progressively more difficult to define what constitutes a great product. Companies are faced with the challenge of how to bring together the organizational functions and processes that make up product design in a way that efficiently delivers final products that are greater than the sum of their parts as defined by effectiveness, safety, compliance, and quality.



# Addressing evolving demands today

Companies today have been working continuously for years to implement design authoring process improvements and digital simulation tools across their organizations in view of rapidly growing need to address need for increased productivity, predictability, and product comprehension in the face of evolving regulatory and customer demands. In the efforts of companies to take methodical steps toward digital adoption, leaders have worked over the past decade to give their teams their own individual toolsets to leverage and optimize their specific job function.

In a space so fundamentally rooted in patient safety and wellbeing, medical device companies understand that there is no margin for error for delivering safe, best in class products, nor is there time to delay their delivery due to internal processes. At the same time, they know the circumstances driving market demands are changing even as decisions and investments are being made to address them. With every technological advancement, design and regulatory compliance become more complex. In response, leaders have to hope that digital implementations are not swiftly rendered obsolete as this evolution unfolds. They make these investments with the utmost vigilance and consideration for how every individual solution adds benefit compared to what risk they may pose and how challenging they are to implement.

As these toolsets are adopted in piecemeal, every functional area of design is comfortably leveraging their own point solutions for their job function, from which they have extrapolated their own processes and best practices. They focus on leveraging these tools to the best of their ability based on their own data and knowledge and pass it on to the next stage of design. These groups may have little visibility into the process that came before them, nor can they control the level of understanding of their own work amongst the group after them.

### Slow and Steady Does Not Win the Race

Adopting point solutions one by one may feel to leaders like a way to thoroughly evaluate the digital investments of the company and move the needle on digital transformation in a way that does not pose undue risk. However, without a concerted effort to connect tools and processes across the organization, undue risk may be the outcome just the same. The true impact of these disjointed point solutions is a lack of cohesion in the overall design that hurts the quality of that design overall.

As every functional area looks inward to execute the processes and deliverables they are measured on, they lack the visibility to see the bigger picture of how their data is used downstream. As a result, they lack capability for robust collaboration needed to drive practical and cost-effective innovation that rises to the new standard of regulatory demands. Giving teams disjointed tools and methods further perpetuates the existing communication siloes between departments. Process mastery of design authoring cannot be achieved with world class tools alone. Leadership can spend time and resources devising an organizational strategy to overcome evolving customer and regulatory challenges. However, it will never be addressed effectively if not predicated by the functional and digital unification of the end to end product design process.

### The Future of Design is Collaborative, Comprehensive, & Predictive

In order to gain a competitive edge as well as drive optimal product functionality, companies must orchestrate their tools and processes in a single, overarching architecture. This entails a culture shift toward functional areas relating to one another and working collaboratively across disciplines toward a single goal as opposed to in siloes against many disparate goals. Organizational leaders must focus on integrating tools, processes, and teams to drive this shift. Through this approach, companies enable success in addressing mounting product complexity in a manner that is futureproofed to deliver safe, effective, and compliant products to patients as demands change. Additionally, organizations will be able to model solutions and patients to understand and predict performance before committing to design and thereby improve patient outcomes.

When approaching digital adoption, it is critical that leaders ensure their toolsets are not only world class but capable of integration and intelligent communication across the chain of command. They must also ensure that their digital partners are prepared to support true implementation rather than simple installation to mitigate risk. These partners should work with the whole of the organization to adopt cohesive processes aligned with new digital investments. With integrated tools, processes and teams working toward a holistic common goal powered by a comprehensive digital twin of product and processes, companies enable:

### Greater Design Integrity

The ability of tools to exchange data directly eliminates administrative burden and the associated opportunity for mistakes and miscommunications that could slow the process further down the line. Harmonizing their company-wide design strategy and feeding insights into a single ecosystem will facilitate communication and collaboration in and across teams. This will in turn enable greater productivity and a smoother transfer of design into production, improving quality and reducing compliance and safety risks.

### A Comprehensive Digital Evidence Strategy

First and foremost, an accurate real-world simulation of both products and the patients using them will provide a critical opportunity to monitor and protect the patients who rely on medical devices. A digital twin of product will not only model devices, but can also model patient anatomy to simulate real-world performance and increase the fidelity and accuracy as a result. In one example, a maker of respiratory care devices was able to successfully use digital twin to predict clinical performance of their devices, helping reduce the time and costs of physical testing and clinical trials.

Furthermore, a continuously scribed lifecycle in a single view shifts risk management from a secondary process sitting between design and validation to an overarching process that can be monitored and addressed throughout the product lifecycle without slowdowns. Creation of a digital thread of traceability across a product lifecycle will be crucial for preparedness in the instance of an audit, adverse event, or product recall as regulatory burden grows. These capabilities together provide an unparalleled level of control to protect patient safety in a post-market environment.

### A Ledger of Institutional Knowledge

A running concrete history of design in context enables design controls to be effectively re-used to reduce complexity and meet regulatory demands. This level of oversight immediately offers organizations agility and confidence to activate on more opportunities in parallel. They do so with the reassurance that complexity can be handled at scale even as design requirements change. Furthermore, as products continue to become more iterative and complex, automated instantiation of processes will position companies to re-use their existing institutional knowledge to iterate and build on product innovation without the need to repeat costly product tests. This in turn ensures a deep understanding of a product's quality, safety, and regulatory compliance based on well-documented expertise.

Program complexity is the common symptom for many root causes that lead to challenges with medical device design. The path forward is exciting with ample opportunity to deliver innovation to patients and providers that will change the way we deliver health care. Orchestrating and integrating design processes will lay the groundwork for delivering on those opportunities no matter how great the complexity becomes.

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