Smart Engineering 2.0 for Medical Devices

The healthcare industry's steady shift to evidence- and value-based care puts pressure on medical device manufacturers to continuously improve products and document their efficacy in improving clinical outcomes and patient wellness. Device makers who adapt to these industry forces quickly and deliver unparalleled performance at optimal price points are going to emerge as winners.

Achieving these levels of quality with agility requires simplifying the complexity of product development. Conventional stage-gated processes are inherently constrained by trade-offs that often result in multiple iterations to satisfy product Critical To Quality attributes (CTQs), leading to cost overruns, launch delays and erosion of market share.

At Cognizant, we can help your organization overcome these challenges with our unique Smart Engineering 2.0 Framework and proven expertise in the medical device industry.

Cognizant's Smart Engineering 2.0: Speeding Better Devices to Market

Smart Engineering 2.0 is the next wave of engineering processes for new product development. It is a unique framework and discipline that drives product development effortlessly in an immersive collaborative environment (see Figure 1). The core foundation of Smart Engineering 2.0 is Model-Based Design (MBD). MBD enables design teams to communicate in real-time using predictive models. MBD, coupled with ICH Q8, Q9 and Q10 guidelines, provides a unique way to optimize the product commercialization life cycle.

Model Based Development and Smart Engineering 2.0 will provide your organization with these benefits:

- Validation of error-prone functionality early in the product development, significantly reducing costs and accelerating time-to-market.
- Productivity gains achieved through automating tasks.
- Proactive risk mitigation helps ensure safe and reliable products.
- Robustness of product design that delivers high quality to patients and health care providers at affordable price points for high value.
- Data collected during the design stages leads to predictable outcomes in manufacturing.
- Changes can be verified before they are actually implemented, leading to safer products and predictable outcomes.

Smart Engineering 2.0 plugs seamlessly into your existing ecosystem and enforces the application of modeling and simulation tools at every stage of the product development life cycle (PDLC) to reduce costly iterations, accelerating product development and optimizing performance.

Smart Engineering 2.0 V Model Framework for Medical Devices

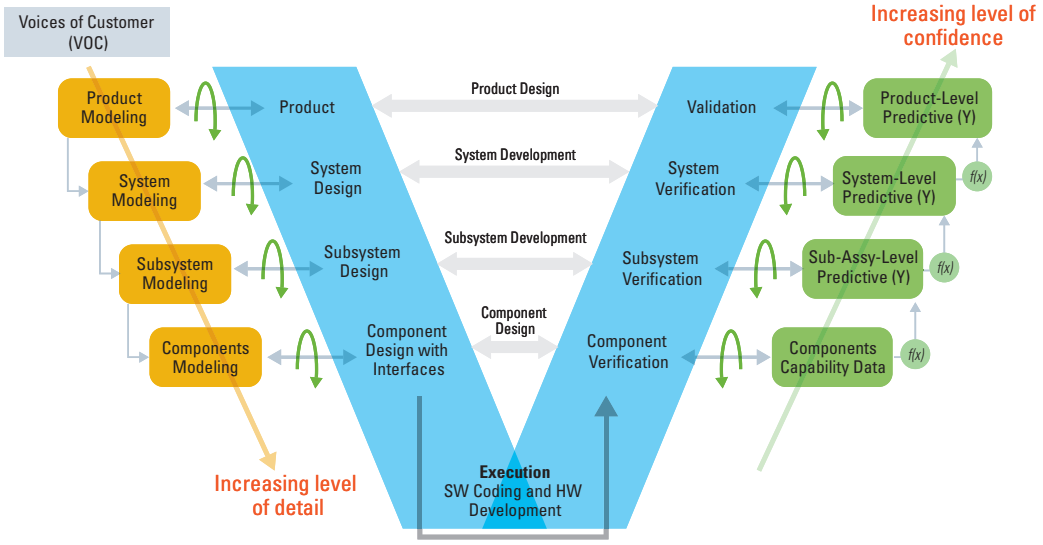

Figure 1

Smart Engineering 2.0 enables design teams to communicate in real time using modeling and simulation tools at each development stage to reduce costly iterations, streamline testing and accelerate time to market.

Model-Based Design Automation

In a model-based context, the evolution of a robust design largely hinges upon the tight integration of requirements to CTQs and predictive performance. Essentially the model definition and simulated output drive the standardization of design cascade and integration of sub-systems. Simulating the impact of inputs on outputs at early stages helps to quickly iterate critical parameters and visualize the impact of the changes on CTQs and manage the product risk within acceptable levels. As a result, there is a significant reduction in expensive and time-consuming testing of physical artefacts at the end of iteration.

The following table illustrates the traditional approach vs. model based design for Medical Devices New Product Development.

ASPECT	TRADITIONAL APPROACH	MBD APPROACH
Requirements	Formal written requirements	Requirements communicated by using models
Design Realization	Primarily achieved using physical artifacts	Primarily achieved using models
Integration	Discrete stages in the PDLC	Throughout the PDLC
Verification	Often performed at phase ends	Throughout the PDLC
Validation	Validation conducted using developed product	Performing models help in early validation
Manufacturing Process	Starts later in the PDLC leading to issues	Data collected during the design stages acts as a continuum for manufacturing minimizing issues
Lifecycle Management	Reactive; Based on events	Continuous improvements throughout the PDLC

Figure 2

Systems Engineering & Predictive Modeling

The quality function deployment (QFD) technique helps to translate the voice of customer (VoC) in to technical product requirements. Use cases are effectively modeled throughout the PDLC from concept to the design validation to ensure the product meets its intended use without trade-offs on the CTQs. Intended use validation and requirements verification are achieved through operational models. Design verification is achieved through subsystem and system simulation. Verification is expedited by generating test cases automatically from the models. Meshing reliability models with predictive experiments with feedback from actual verification allows engineering teams to significantly enhance design quality, robustness and optimization of CTQs at the end of the verification and validation (V&V) phase. Modeling can also convey manufacturing process parameters, simulate a software module or the entire subsystem or emulate a real world usability scenario.

Cognizant's Expertise: Medical Device New Product Development with Smart Engineering 2.0 Framework

Plug Smart Engineering 2.0 into action on your next product development cycle and reach the market ahead of your competitors. . Cognizant's medical devices engineering practice has experience across end-to-end product lifecycles and expertise spanning therapeutic domains including heart valves, pacemakers, ICDs, scanning equipment, respiratory/anesthesia devices, scientific instruments, energy-based generators, dialysis machines, electro-mechanical surgical devices and in-vitro diagnostics equipment.

Our system architects, product engineers and design analysts have rich experience in the following areas of medical devices product development.

- Systems engineering and model-based development.
- Embedded hardware and firmware design, integration and test automation.
- Software application development and test automation.
- Mechanical systems design.
- Product risk management and reliability modeling.
- Device analytics.

Our experience also encompasses expertise in the following technology applications implementing Smart Engineering 2.0, including but not limited to:

- MATLAB
- Simulink
- SystemVision
- Rational Rhapsody
- Enterprise Architect
- Stateflow
- SCADE
- Eclipse UML
- SPICE
- PSIM
- MultiSim
- 3D MCAD
- ECAD
- CAE

Cognizant has also developed a test design automation accelerator tool, ADPART™ (https://adpart.cognizant.com). ADPART™ takes a model/workflow as an input and helps generate the optimal number of test cases for a system.

Cognizant: Helping customers deliver market leading products and performance

We can help your company develop superior medical devices and IVD equipment. Cognizant's industry leading position and solutions have helped our customers across the industry landscape to optimize development efforts by as much as 40%; shrink design cycles up to 35%; accelerate time-to-market by 30%; and deliver products at 40-50% lower price points. Our medical devices business, clinical and technology experts leverage leading-edge technologies, state of the art labs, innovative development frameworks, accelerators and alliance partnerships to help your company surmount today's industry challenges and achieve a market-leading position.

For more information about Smart Engineering 2.0 and how it will help your organization accelerate the development and introduction of high quality, clinically effective products, please contact:

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About Cognizant

Cognizant (NASDAQ: CTSH) is a leading provider of information technology, consulting, and business process outsourcing services, dedicated to helping the world's leading companies build stronger businesses. Headquartered in Teaneck, New Jersey (U.S.), Cognizant combines a passion for client satisfaction, technology innovation, deep industry and business process expertise, and a global, collaborative workforce that embodies the future of work. With over 100 development and delivery centers worldwide and approximately 218,000 employees as of June 30, 2015, Cognizant is a member of the NASDAQ-100, the S&P 500, the Forbes Global 2000, and the Fortune 500 and is ranked among the top performing and fastest growing companies in the world. Visit us online at www.cognizant.com or follow us on Twitter: Cognizant.

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