VIEWPOINTS ON INNOVATION

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Digital Thread and Smart Connected MedTech

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In a constantly evolving regulatory landscape, life sciences manufacturers are currently being pushed to implement systems that connect the enterprise, the value chain, and the product at every stage of its lifecycle. Standards and regulations like ISO 13485 & 14971, FDA's Quality System Regulation, and EU MDR/IVDR set expectations for companies to embrace the digital thread while verifying the risk/benefit ratio in a closed-loop fashion.

The digital thread has great potential in life sciences because it enables a seamless flow of data across the value chain, connecting clinical, product development, manufacturing, and post-market surveillance data.

However, there are challenges. Digital thread maturity is sporadic, and most companies are generally immature. Many still use paper-based or point systems. Most companies have no overarching enterprise architecture or digital thread roadmap to guide them based on strategic imperatives, compliance mandates and market demands. Others lack governance and rely on uncoordinated skunk works band aids to fix their problems. Rampant acquisitions and divestitures further exacerbate these challenges.

World class companies are already enabling the digital thread by leveraging the power of Internet of Medical Things (IoMT) and digital quality management systems (QMS) that connect the buyer, provider, patient and manufacturer. IoMT is estimated to save the healthcare industry $300 billion annually.[1] Instead of using multiple point systems to achieve EU MDR/IVDR compliance, Digital QMS can consolidate everything into one single source of truth. And advanced analytics applied to that data can improve products, speed development times, increase production yield and revolutionize field service.

Now is the time.
Companies that want to remain competitive must move forward on their digital thread initiatives.

This compendium contains helpful advice on leveraging the power of smart connected products and systems, using advanced analytics to improve quality, and using digital QMS to foster a culture of quality that ensures the delivery of more effective, safer products that improve patient lives.

[1] https://www.businessinsider.com/goldman-digital-healthcare-is-coming-2015-6

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The Digital Thread in Life Sciences

Understand an end vision for the digital thread, demonstrating its ability to enable a seamless flow of data that connects the product development process, including research, design, manufacturing, testing, quality, monitoring and servicing.

Connected Products

Connected devices enable new business models by connecting patients to manufacturers. Learn to leverage the power of IoMT (Internet of Medical Things) to generate valuable busines insights and win in competitive markets.

Machine Learning & Advanced Analytics

Democratize analytics to build and adopt advanced capabilities with predictive analytics, machine learning and artificial intelligence. Apply AI and automation to improve products, speed development times, increase production yield and revolutionize field service.

Closed-Loop Quality & Compliance

Simply focusing on maintaining compliance is not enough. Unify quality processes and data across the product lifecycle, fostering a culture of quality that ensures the delivery of more effective, safer products that improve patient lives.

Digital Thread in Life Sciences: The Future of Product Innovation

by Shamina Merchant, Leo Moran and Dave Hadfield

Our world changes daily in front of our eyes. Since March, the world has been upended by COVID-19. It confines us to our homes, dominates every conversation, and changes how we live our lives. As businesses reopen in phases, we are redefining what our new normal will look like in the coming months and how this experience will change our lives in the years to come. Will we eat out as often? Maybe grocery and food delivery apps will become a permanant preference. What about school – will more students embrace online learning moving forward? Among all uncertainty, one thing is for certain... the future will be increasingly digital.

The Shifting Landscape in Medical Device

The open questions about the future are not unique to our personal lives. It's clear that today's challenges will drive lasting changes in the way we all work, especially within industries that are directly affected by the pandemic.

Imagine **Susan**, a 43-year-old mother of two. She has worked in the medical device industry since 2002 and has experience in various stages of the product lifecycle. Currently, she serves in a product management role and has spent the last two years developing a plan for the next big product for her $2.2 Billion medical device company, Kuality Kare.

In March of 2020, the world she knew was turned upside down, and her focus became firefighting through a situation she had not yet had a chance to process. There were a million questions she didn't have the right answer to, and no textbook example to hold up as a leading practice.

How long would the freeze on elective procedures last? Should they rush to release the new device they'd been working on? How could she work with the FDA to make this possible? If it came to it, how would her team equip their distributors to get essential products to the most vulnerable cities to fill the rising global demand?

But more immediately:

How could she find the best tool for remote work? Was there anything she could do to limit how many of her employees had to go into the office?

And as if she didn't have enough on her plate already:

How did the quadratic formula work again? She needed to help her son, Ryan, prepare for his Algebra 1 test… and, of course, he would be taking it from home.

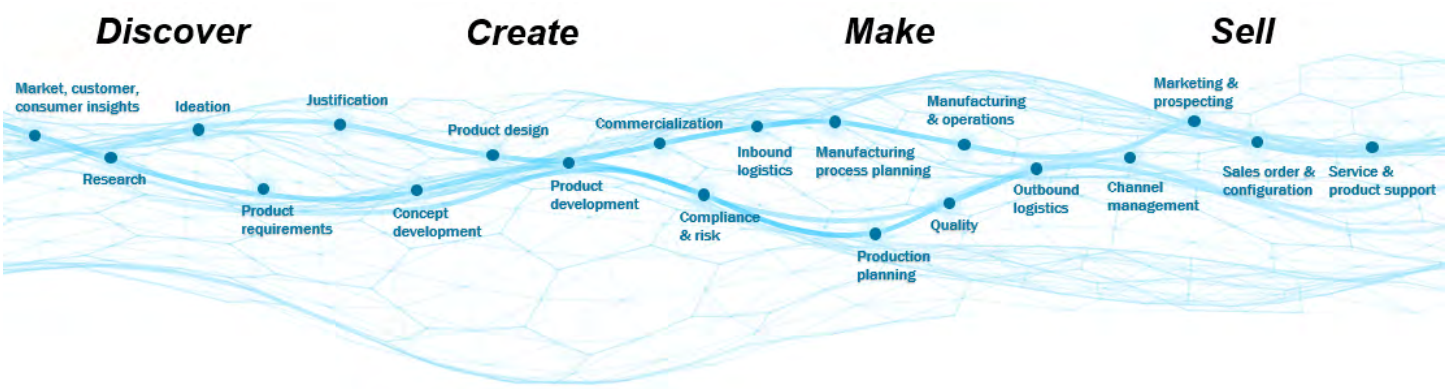
Susan's story is not unique. Companies across the medical device industry were disproportionately impacted due to the pandemic. Early in 2020, as healthcare organizations initially braced themselves for overcapacity, the industry struggled to keep up with the rising demand for essential products while also struggling to adapt to the implications of halting elective procedures. The industry reeled as workforces became remote overnight. For many, protecting employees came at the expense of effective collaboration. This not only impacted product development and manufacturing, but sales, training, and product servicing, as much of the industry was underprepared to solve challenges traditionally resolved in person in this new remote working environment.

It is clear that the companies who focused on building their digital capabilities in recent years have had a significant advantage in adapting in response to this crisis, but what does this signal for the future?

According to the Harvard Business Review, in 1958, the average lifespan of companies listed in Standard & Poor's 500 was 61 years. By the 1980s it was down to 25 years. Today it is less than 18 years. The reason for the sharp decline? The rate of change in the world has increased dramatically due to digital transformation. Life Sciences organizations must embrace digital transformation if they are to survive in this rapidly changing world.

Redefined Possibilities: The Digital Thread and the Digital Twin

So why do some companies fail to embrace a digital world while others thrive? The organic evolution of processes and technologies has resulted in a disjointed experience within the product lifecycle, from discover to create to make to sell. The solution is the digital thread.



If the value chain represents all the activities that a company completes to deliver a product to the market, then the digital thread is the fabric that holds it together. The stronger the fabric, the stronger the value chain. The focal point of the digital thread is the digital twin, or the virtual representation of the physical product. The digital twin can be used in design, testing, monitoring, servicing, and other functional areas to augment product management capabilities.

Reimagining Product Innovation with the Digital Thread

To examine how the digital thread enables innovation in the face of great challenges, let's jump back to the present and check back in with Susan and her colleagues at our fictional medical device company, Kuality Kare. In this scenario, we assume they have a modern digital infrastructure in place, and this dramatically improves their ability to innovate and deliver.

KUALITY KARE

Using advanced analytics, Kuality Kare has identified a market need brought about by the pandemic. With minor changes to an existing product, they can help fill this crucial gap. If Kuality Kare can act quickly, it can help the world combat the pandemic and serve shareholders by offsetting lost revenue to their elective surgery products busi[illegible] s investing in its digital capabilities, so Susan feels c[illegible] challenge.

S[illegible] product design. He re[illegible] s – which integrate se[illegible] M) systems – and B[illegible] th traditional file-based CAD systems that limit collaboration. His rapid adoption of game-changing new features – like the ability for his design team to collaborate on the same CAD model in real time – allows them to iterate quickly as they adjust an existing product's design to fill the identified market need.

This CAD model is the basis for the digital twin – a concept that Susan is pushing at Kuality Kare. Digital twins come in a variety of forms, often incorporating several discrete models threaded together. These representative models can be composed to work together, allowing organizations to simulate an object's behavior in a specified digital environment, subject to a known set of assumptions and conditions. Applying physics-based digital simulations feed incredible insights to product design that do not require the time and expense of physical prototype creation and testing.

Susan's intern **Rachel** has set up a demo to show the team how their 3D CAD models can easily be loaded into an augmented reality application, further expanding the use of the digital twin. Rachel explains how this would allow for a virtual product review that leverages the digital twin for an accurate and informed session in which reviewers need only their phone to participate. These models can then be leveraged again later in the product lifecycle to help with sales, training, and servicing.

Key Elements of the Digital Thread

Susan takes a deep breath. She knows that the strong digital infrastructure at Kuality Kare will help her team quickly get this new product to market and support patients in crisis.

Her son has started back at (virtual) school, and as she watches him work through math problems, she thinks through some key elements for success as her team prepares to release their product.