

cover story

# Medtech's path to digitalization

How the medtech industry can change to embrace a new era of digitalization and why the time is now.

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Adopting modern communications and computer technology in industrial settings can be difficult, especially for the highly regulated medtech industry that uses many legacy, customized systems.

Medtech manufacturers aim to maximize supply chain profitability and build high-quality products, with many using lean manufacturing techniques.

However, these traditional methods take immense time and effort to reach maturity. Actions follow a reactive, stop-and-fix approach. Machines, tools, and products in modern manufacturing plants are much more sophisticated than they were when lean methods were launched and, as process flows become increasingly complex, this linear approach is no longer sufficient. Manufacturers using only traditional lean manufacturing methods have reached a barrier that requires a new way forward.

Industry 4.0 (I4.0 or the 4th industrial revolution) focuses on improving process efficiency to deliver high-quality products at lower cost. However, high product margins in the medtech industry reduce

the motivation to change. For businesses that want to remain competitive, they can't afford to ignore the benefits these new technologies offer.

Using **digitalization** (<https://www.criticalmanufacturing.com>) to access and understand the right data presents a new opportunity for a step-change in quality, above what can be achieved through lean or Six Sigma.

## Path to digitalization

Manufacturing is often regarded as a rigid, human-led operation with fixed process steps and a focus on local key performance indicators (KPIs), preventing a progressive vision for the entire value chain. In medtech, masses of information are still stored in paper and legacy systems, preventing a real-time, dynamic approach. Harnessing the benefits of I4.0 requires a roadmap, the roots to which lie in applying a digital mindset to existing manufacturing operating systems.

The move to Big Data, the Internet of Things (IoT), distributed intelligence, artificial intelligence (AI), and completely autonomous systems is costly and complex and requires careful, strategic planning. Many medtech companies have grown through acquisitions and inherited different systems.

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The maturity level of different plants may vary significantly, with some still relying on paper processes. This makes it challenging to understand where to prioritize transformation.

“An IT approach may be to standardize systems, but in a manufacturing environment, it’s difficult to take things out because they are so embedded in processes. A different approach is required to modernize and digitize manufacturing,” says Paul Straeten, head of manufacturing IT at Medtronic. “We have done a lot of analysis of revenue, value, and cost across different sites to understand our priorities.”

With the right vision and strategy, the path to making I4.0 a reality isn’t as terrifying as it may first appear. I4.0 uses existing technology and connects information and systems to gain visibility and understanding of the complete value supply chain. The first step to this is data and having better information to predict markets and make better decisions.

Strategic development objectives must be defined. Where does the business want to be in three years and how does it get there? Key capabilities and commonalities between plants can be identified (it's better to get 1% improvement across five plants than 3% in one). By understanding the level of maturity of existing products and systems across different plants and areas of cohesion, leaders can prioritize investments and create a sequence of what the journey to I4.0 will look like. They can then identify technology gaps, creating a plan for common architecture and standardization between plants.

## Data to information

Machines, sensors, operators, and products, along with the wider supply chain and external related sources, generate data. However, few manufacturers use this to gain insights into operations and processes. Even analog signals from older equipment can be digitized to incorporate them into modern systems. If we can collect, collate, and contextualize all data that relate or influence manufacturing operations, we have the building blocks to move from reactive to predictive operation.

“Medtronic has grown significantly through acquisitions,” Straeten says. “The manufacturing sites have processes and systems implemented that are aligned with our quality management system. But how the data is stored and managed is a very diverse landscape, which adds enormous complexity. It's one of our key challenges.”

The path to autonomous manufacturing started many decades ago with computerization, so it becomes easier to see how this progression can continue to meet new objectives. Following computerization, plants progressed to tools that provided visibility of the shop floor, providing deeper insight into areas such as individual machine productivity. Today, as we make better use of this data, we are moving to a stage where information can be used to predict what will happen, enabling prepared responses to be formulated.

Ultimately the aim is a completely self-adapting system that requires no human intervention. If we can get the right information from the data, AI algorithms and machine learning tools can use it for predictions and autonomous operations.

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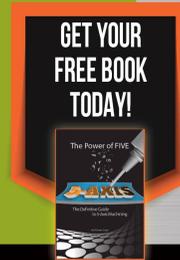


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Once the right data are captured, we can gain insight and foster an appropriate response. When an event occurs, sensors detect what's happening. It takes time to understand and analyze the data. It then takes more time to decide on a course of action and follow through. Every second lost in this flow of events costs money. I4.0 technology can shorten that sequence, providing much quicker insight into what the data mean.

New intelligent manufacturing execution systems (MES) are the backbone of autonomous systems. The software can add needed context for data and connect disparate data sources and systems. It integrates legacy equipment with new, distributed edge-processing devices and brings data together to give a complete picture of a smart, digital shop floor. It also provides a common interface and ensures business procedures and quality processes are not bypassed as the system becomes more automated. Paper records will become obsolete as all process information is gathered and stored in electronic device history records (eDHR). Data can be securely accessed from anywhere, and compliance becomes part of the manufacturing process instead of reactive procedure.

## Summary

Technology has progressed enormously, but many medtech manufacturers still use outdated systems and manual processes. Increasingly sophisticated and complex products, combined with more stringent regulatory requirements, require us to embrace digitalization to remain competitive. Once a company understands where it is in the process and where it wants to be, it can start taking the necessary steps.

The path to I4.0 is progressive, using legacy systems and IT infrastructure already in place, but it's a step change in manufacturing. A modern MES enables integration of old and new, bringing together disparate systems, information, and communication protocols into a single source of truth that provides a backbone for progression to greater autonomy and smart manufacturing.

Medtech companies must start making digitalization part of their DNA or they risk being left behind. I4.0 is a journey we have all been on since the dawn of computers. Evolution or revolution, extinction cannot be an option.

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