Has COVID-19 Created a Tipping Point in the MedTech Industry?

The pandemic has revealed that the medical device industry is still behind in technologies that allow them to respond to change, be agile, and quickly manufacture products at high quality.

by: Chris Parsons in Automation & Motion Control, COVID-19, Medical on May 13, 2020

The coronavirus pandemic has been one of the greatest tests for the MedTech industry in modern time. The global effects have left many industries reeling and asking questions about how their business can react in times of crisis. For medical device manufacturers, this event could be a tipping point to embrace digitalization and Industry 4.0 (I4.0) production technologies.

"Clinical Diagnostic, Medical Device companies are committing significant resources to support the fight against COVID-19. However, many of these organizations are facing challenges managing their business in this new virtual and remote reality. The demand for organizational effectiveness, visibility and control in a disrupted environment represents a watershed moment for the modernization and digital transformation in our industry," said Daniel Matlis, president of life-science industry analyst firm Axendia.

As with any crisis, COVID-19 has put a spotlight on the need to respond to market demand for essential devices. For this event, this has been the need for personal protective equipment (PPE), ventilators, and other emergency medical equipment. The sudden and urgent need for these has meant that other industries, including automotive and major electronics manufacturers such as Tesla, Ford, GM, Dyson and Apple, have stepped up to fill the demand for medical devices. With the right systems in place, however, could medical device plants have responded better to the pandemic?

Many MedTech plants are inefficient. They lack visibility through the whole production process and are limited in their ability to increase capacity or throughput. They cannot easily ramp up production, activate new lines or transfer production to other facilities while maintaining adequate control of quality. This makes it difficult for them to respond to a sudden change in market demand, such as that created by COVID-19. However, the technology is ready, available and proven for them to rectify this.

In the medical device industry, the proliferation of digital and mobile health devices along with the Internet of Medical Things is enabling smart connections between technology, people, processes and data that support patient-centered healthcare and drive improved outcomes. (Image source: Critical Manufacturing)

"Medical Device companies must leverage modern manufacturing and smart-sourcing technologies to enhance visibility, control and collaboration and drive resilience and agility across the value network, from raw material to the patient," said Matlis.

Based on the Industrial Internet of Things (IIoT), the I4.0 manufacturing model enables more efficient production, provides the agility required to quickly and easily customize products, facilitates faster new product introduction, and provides better quality assurance. Using low cost smart-sensors, I4.0 distributes intelligence throughout the plant(s), enabling materials, products and machines to negotiate with each other to improve availability and quality.

This moves manufacturing away from straight production *lines.* Instead, intelligent products and materials, termed as "cyber-physical systems" (CPS), communicate directly with intelligent machines, or "cyber-physical process systems" (CPPS) in a dynamic marketplace. The CPS requests services from the CPPS and can select the most efficient route to complete its processes. For example, if one machine requires a change to its setup or recalibration, the CPS simply selects a different machine that is ready to provide the service it requires.

MES is the backbone of I4.0

Having smart products, materials and machines generates a lot of data. This 'Big Data' holds a lot of value but only if it has context. A critical part of this new approach to manufacturing, therefore, is a future ready Manufacturing Execution System (MES). A modern MES system which, unlike traditional MES, is based on decentralized logic, ensures all business, quality and regulatory steps are enforced and all systems fully integrated.

The manufacturing execution system (MES) makes shop floor information widely accessible, allowing teams to respond more rapidly to changing requirements and conditions. (Image source: Critical Manufacturing)

It proactively and systematically standardizes and enforces processes across all sites. The MES also provides a single source of truth; aggregating, contextualizing and analyzing data to provide more in-depth insight into manufacturing processes. It can include integrated scheduling and maintenance so that a job or part isn't scheduled unless the source inventory is available, the machine properly maintained, and the right tooling ready. This increases

uptime and further drives production efficiency.

Holding and analyzing data from the complete manufacturing supply chain, the MES provides real-time visibility of production. Shop floor information is made available to the rest of a company, allowing them to respond more rapidly to changing requirements and conditions. Business Intelligence KPIs, such as production volume, throughput, quality, cycle-time, and inventory figures, can be presented in customizable charts, dashboards or reports.

Having all data in one place means this can be used to create a 'digital twin'. A digital twin can be defined as: A virtual, computer-based copy of something real, modelled to realistically represent and control physical assets through their lifecycle and be easily accessible at any time, and the concept holds many different benefits for manufacturers.

Data flows from the physical objects on the shop floor to a virtual copy, that can be represented in 2D or 3D form. This enables visualization and control of products, processes, specifications and attributes to enable optimization of quality. It identifies value-add and non-value add production steps and processes to help tune production efficiency. Alongside helping with production quality and efficiency, the digital twin also aids traceability and new product introduction, where quick feedback and complete information helps to accelerate the introduction process. It further opens up virtual reality (VR) and augmented reality (AR) scenarios to help with training and operator / maintenance tasks.

Advanced Analytics: Descriptive, Predictive and Prescriptive

The modern MES has the capability to use more complex statistical and machine learning techniques to perform advanced analytics. Using machine learning, the huge datasets captured in the system can be used to train neural networks to predict improved outcomes based on historical and current data.

This creates models of future performance and behavior based on past data, including predictive and in a near future prescriptive models. Although predictive maintenance offers a clear and obvious ROI in this area, there are many other opportunities for improving performance and efficiency of a factory. Indeed, the only limit on this technology at present is the imagination of what to do with it.

Getting Rid of Paper

Getting rid of paper records makes so much sense in so many ways for MedTech companies. Paper inherently means a retrospective view of the process. It necessitates that any errors

or quality issues can only be dealt with after a manufacturing step. Using real-time data and fast analytics, the MES can flag exceptions as they arise, enabling swift action to be taken to correct issues in real time. This not only builds quality into the product, but also facilitates continuous process improvement for even better efficiencies and production excellence to improve product quality.

The future for MedTech is clever and bright – and it does not involve mountains of paper. (Image source: Critical Manufacturing)

As the MES can automate many manual processes and has all production data from the CPS and CPPS flowing through it, it becomes a complete electronic device history record (eDHR) and removes the need for paper records.

Using eDHR means traceability is simply part of the process and can even integrate the wider supply chain. It removes the possibility of manual errors and increases confidence, both internally and with regulatory bodies, in manufacturing processes. In turn, this means records can be searched and found immediately and audit processes become much less painful. Compliance simply becomes a by-product of continuously improving manufacturing excellence.

What's more, paper cannot be sanitized, so paper processes during a pandemic represent unnecessary risk to workers. Moving to a paperless system may well mean the difference between being able to continue production or not during a future similar event.

A Tipping Point?

Most MedTech companies have not implemented a modern MES solution based on I4.0. The reasons vary but often a reliance on existing legacy systems and fear of disrupting complex manufacturing processes that have evolved over time is at the root. The levels of efficiency and agility to be gained, however, make a clear business case for change.

In the wake of the COVID-19 outbreak, many companies will realize they were not prepared for such an event and understand the need to make their business more resilient for the future. Surely

this has to be the tipping point for change.

“Based on discussions with Medical Device Executives, it is evident that those organizations that invested in Modernization and Digital Transformation are well positioned to navigate the current disruption, while those dealing with paper will need to play catchup,” said Matlis.

The thing that many companies do not realize, however, is that a pathway to I4.0 may not be as torturous as they expect. The future ready MES offers a way to integrate the old with the new and implement a smart manufacturing system at a pace that suites business needs.

Other considerations after dealing with the coronavirus include the safety of employees and other people. Implementing a modern MES reduces reliability on people in production processes and enables business operations to be sustained through remote access, automated reporting, electronic data exchange and real-time factory controls. It minimizes the number of onsite shop floor staff by precisely scheduling work, dispositioning materials, and monitoring equipment for output, quality and maintenance issues in real-time.

Modernization is not about reducing headcount, but lowering reliance on inefficient manual process, working smarter and removing error-prone, mundane tasks so that human assets can be reallocated to high value activities. This could reduce opportunities for error throughout the complete supply chain. Furthermore, moves by the FDA to encourage electronic records will surely be reinforced as they encourage more electronic/remote inspections and audits.

A Dynamic Market Requires a Dynamic Solution

As discussed, a modern MES can provide a pathway to a smart factory. It should be able to integrate smart devices and legacy equipment, to enable a controlled changeover to I4.0 with minimized risk to current business. The other thing it must provide is the ability to evolve with business into the future. Afterall, what is the point of changing to a system that helps the business be more responsive to changing markets if the system itself cannot adapt to those needs? To this end, a modern MES solution is not a legacy system with a new wrapper; it is a system designed from the ground up to operate in a I4.0 world with modularity and complete scalability.

Summary

The Medical device industry is still behind in technologies that allow them to respond to change, be agile and manufacture products quicker at high quality. “Medical Device companies must leverage modern manufacturing technologies to enhance visibility, control and collaboration and drive resilience,” said Axendia’s Dan Matlis. Real-time production monitoring is usually held out as an example of the ultimate in manufacturing control. Today it stands out as a critical tool for production continuity with a minimum of onsite workers. Intelligent handling and analysis of data gives deeper insight into processes.

COVID-19 has shown
producers that they need
more resilient systems.

When an event such as this occurs, MedTech products still need to be compliant and safe, despite urgent demand to ramp up production. A modern MES offers greater efficiency, flexibility and agility to deal with the unexpected, while making regulatory compliance easier and facilitating the possibility of electronic inspections and remote audits.

Modern MES will improve patient outcomes. (Image source: Critical Manufacturing)

Ultimately, COVID-19 has created a tipping point, whereby MedTech companies are realizing why current systems are insufficient and will start to make investments in future-ready technology that will protect and strengthen their business going forward.

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