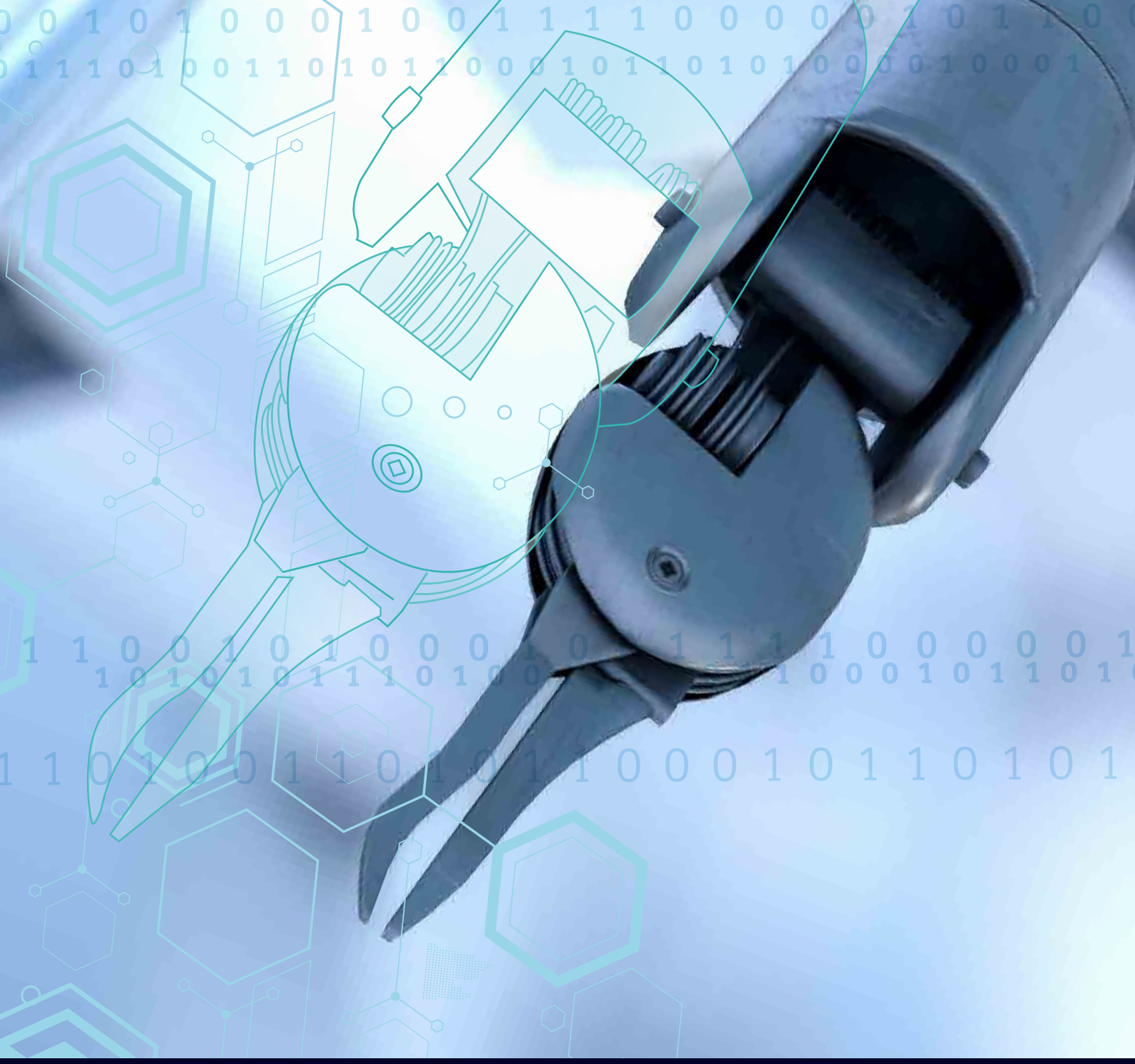

Siemens Digital Industries Software

The cultural shift to smart manufacturing in the medical device industry

Medical device manufacturers use **Siemens solutions to enhance processes**

SIEMENS

Abstract

Medical device companies realize that smart manufacturing is the fastest way to achieve operational excellence in today's global marketplace. With current world conditions adversely impacting markets and exerting unprecedented pressures on medical device manufacturers, the journey towards smart manufacturing is essential to remain competitive. Accelerating product innovation while at the same time controlling product performance has never been more important.

There are four major steps medical device companies can take to achieve operational excellence: Digital design transfer; produce a comprehensive digital twin to optimize process efficiency and quality; execution of the "5 Ms of manufacturing" (man, materials, machines, methods and metrics) and electronic device history records (eDHR) for quality and process enforcement; and finally, incorporate the Internet of Things (IoT) and manufacturing analytics for data collection, aggregation and feedback into their process.

Digital design transfer

Design transfer, from research and development to operations, is about communication. Functional groups within an organization and their suppliers must communicate in new and innovative ways (digitally) to accommodate modern product complexity. The potential benefit of excellence in design transfer leads to operational efficiency, lower costs and higher quality – all while improving speed-to-market. Operational excellence requires a bidirectional effort using a comprehensive digital twin of production to ensure compliance and design intent with continuous feedback loops for quality and efficiency improvements. Digital threads ensure tracing of data and critical manufacturing characteristics for compliance and safety, while improving supplier collaboration related to product data, design changes and quality controls. One challenge is communicating intent/context in order to preserve design integrity into manufacturing.

With digital design transfer, medical device companies can integrate product design and execution in a single environment. During this stage change can be affected from engineering (the engineering of parts/assemblies) to manufacturing bill-of-materials (mBOM) for manufacturing parts/assemblies to the manufacturing bill-of-process (mBOP). This final change pillar includes BOP steps/operations, resources and documents.

The roadmap for digital design transfer goes from eBOM to mBOM authoring to BOP authoring and enrichment to, finally, approval and release of BOP for production.

Geographically distributed operations are the new normal, making it imperative that medical device organizations unify their global design transfer processes. Powered by an open and integrated platform, Siemens' Design Transfer solution enables high velocity at diverse locales.. Maintaining control at every stage in the device lifecycle allows common change on a global scale, providing the quality required, combined with the required widespread interconnectedness.

Digital twin production

The production of a digital twin offers manufacturing process simulation at every level. A comprehensive digital twin begins with layout design and includes material flow simulation, ergonomics, robotics and virtual commissioning. The digital twin offers medical device companies the design for manufacturing, plant and line simulation and process/workstation simulation.

A digital twin can be leveraged to plan and simulate production processes virtually, solving real manufacturing issues. One Siemens partner that created a comprehensive digital twin enjoyed 30 percent faster time-to-market and saved $2 million in production costs.

Achieving operational excellence is a goal that can seem difficult to attain. Certainly, the past methodologies used in the medical device industry have allowed manufacturers to reach levels of "pretty good" and "good enough," but they would be hard-pressed to be labeled as excellent.

A major way medical device companies can improve their ability to pursue operational excellence is by digitally simulating scenarios in advance. Planning for manufacturing diversification can benefit from simulating material and manufacturing operations workflows as well as quality control operations to plan for optimized production efficiency. This allows teams to identify and eliminate quality problems virtually before real production begins.

Production execution

The execution of the five Ms of manufacturing places an emphasis on quality and process enforcements. During this step, medical device companies implement a tight integration between MES and enterprise resource systems (ERP), enjoy real-time visibility, control and speed throughout the manufacturing process and stay agile by building configurable interlocks into manufacturing.

Medical device manufacturers have traditionally used paper-based methods to guide and track the execution of their manufacturing processes, including creating paper device history records (DHR). Industry leaders have evolved and implemented systems to automate manufacturing execution and manage data related to manufacturing processes as an electronic DHR (eDHR). Others have not yet evolved and are still using paper-based processes. As a result, face challenges in scaling these systems, especially across globally distributed production facilities and when contracting with manufacturing partners.

An easy way for companies to embrace modernized manufacturing processes is by implementing Opcenter™ Execution Medical Device and Diagnostics (Opcenter EX MDD) software into their processes. Opcenter EX MDD seamlessly replaces costly paper and manual processes with self-auditing electronic device history records. Opcenter enables lean manufacturing and gives medical device companies the ability to build quality into their process. It also allows high-level medical device manufacturers to efficiently build their products with full traceability.

Opcenter is a part of the Xcelerator™ portfolio, a comprehensive and integrated portfolio of software and services from Siemens Digital Industries Software. Xcelerator brings together and integrates the entire Siemens portfolio for medical device manufacturers with embedded tools and databases connecting current and future information technology, operational technology and engineering technology environments.

IoT/IIoT and manufacturing analytics

This is the necessary stage of data collection, aggregation and feedback. A Siemens partner was recently challenged with an increased need for digital systems to collect valve data and transmit it to the cloud to make it actionable. They needed a highly-integrated IoT valve that leverages MindSphere®, the Industrial IoT as a service solution from Siemens Digital Industries Software and IoT gateways and cloud-based device management.

The partner realized increased reliability by detecting deviations in real-time and significantly reduced costs by mitigating downtime and leveraging cost-effective measurement and monitoring capabilities.

To succeed in this competitive, complex and individualized market, medical device companies must leverage IoT to pair big data analytics with manufacturing and global supply chains with design and development processes across the entire value chain.

Siemens' IoT solutions for the medical device industry are powered by combining big data with a comprehensive digital twin, or a virtual representation of actual devices, moving in tandem across the lifecycle and connected by digital threads. By connecting virtual development and production planning environments with real support and lifecycle production data, Siemens is equipping med-tech organizations with the transparency and advance analytic tools required to gain a competitive edge using big data.

In addition, 2020 proved that low-code apps are rapidly becoming a go-to solution for not just innovation but also facilitate vital improvements to efficiency, experiences and system integration. Given that Siemens now has a low-code application platform within the Xcelerator portfolio, it makes perfect sense to apply the technology to the medical device process.

Operating in a highly regulated industry

In the highly regulated medical industry, production of medical devices must be tracked to ensure safety and reliability with a variety of processes. Often, these focus on generating paper trails of various documents such as primary validation plans, pilot reports and control plans, whether they are physical or digital.

Medical device companies have begun adopting better tools for automating the management of these documents to help enforce quality and compliance. The existing systems have allowed them to move from paper-based methods to automated workflows, particularly as it relates to enforcing quality processes in manufacturing and capturing a complete and exact history of processes used to create each batch of devices. However, executives recognize the need to balance the potential benefits of these efforts against the strict regulatory oversight required when adopting a new process for manufacturing medical devices.

In view of this regulatory oversight, the ability to improve production quality and efficiency using analytics or simulation to optimize manufacturing has not traditionally been thought of as critical. As a result, there is a natural separation between product development and large-scale production. New innovations in product design must be cleared before they can be manufactured. Medical device companies have become accustomed to production delays as part of the regulatory clearance process.

Siemens' Manufacturing Operations Management (MOM) is a game-changer

Siemens' multi-site enterprise manufacturing operations management (MOM) is designed to provide full visibility and control of manufacturing processes to support operational performance improvements. The solution consolidates all production processes to enable quality management, production intelligence, advanced planning and scheduling (APS), track and trace, process execution and improved workflow.

Within the MOM portfolio lies Siemens' MES solution. This critical piece provides up-to-the-minute reporting of actual manufacturing operations along with a comparison of historic and expected results. Performance results include measurements as resource utilization, resource availability, product unit cycle time, conformance to schedule and performance-to-standards. Performance analytics may include SPC/SQC analysis and can draw information gathered by different control functions that measure operating parameters.

The strengths of Siemens' MOM lie in part with the integration to its product lifecycle management (PLM) solution, fitting well with large discrete manufacturers. This allows manufacturers to take a closed-loop approach to the complete product and production cycle. Siemens' MOM portfolio enables users to use the same smart data from design to production and beyond. Opcenter, meanwhile, unifies and orchestrates its MOM solutions as part of Xcelerator, which can be used to simulate and model the behavior of real-world production systems and the equipment within the system.

Xcelerator provides a way for manufacturing end-users to personalize how they view and consume the vast quantities of data being generated. The digital twin plays an important role by bringing together the virtual and physical (or real) worlds, connecting the engineering and operational domains. The digital twin enables users to obtain better insights from the combined data and produce a highly visual, dynamic digital representation of the product and its production process in operation. Leveraging this comprehensive digital twin, Opcenter enables closed-loop continuous improvements in production.

Increasing design complexity

Although their current processes may satisfy their current needs despite the drawbacks, leaders must realize how the long-term implications of market trends are creating urgency to improve operational efficiency.

Growing demands for contextualized individualized therapies, increased use of home devices and more autonomous devices are driving heightened product complexity. This is compounded by differing regulatory agencies that need to be addressed in globally marketed products, particularly in view of forthcoming requirements like the European Union Medical Device Regulations (EU MDR) and in-vitro diagnostic regulations that are expected to be fully phased in by 2021. Further, some medical technology companies must consider planning and managing for production of devices and an eDHR with a lot size of one as personalization becomes more commonplace.

While keeping pace with product complexity and updated regulations, companies also must account for rapid changes in markets, politics and public health conditions that are in process and continually shifting. Executives will face heightened supply chain risk management issues when ensuring continuity of their supply of devices to healthcare delivery providers. This was the case in a recent executive order mandating essential medicines, medical countermeasures and critical inputs be manufactured in the U.S. As the recent shortages in critical medical equipment have proven, companies failing to plan for supply chain disruption will not be able to respond to changing conditions.

Additionally, the ever-increasing competitive pressure stemming from a variety of healthcare delivery market changes are forcing companies to improve speed-to-market and predictability.

In view of these challenges, companies face extreme scalability challenges around transferring personalized, patient-specific design elements between product engineering teams, manufacturing engineering teams and operations teams and their supply chain partners. It will become increasingly challenging to keep pace with efficiency standards set today – let alone improve them – while maintaining compliance and safety. This obstacle will persist and prevent companies from delivering products to market unless they can find ways to shift from managing static documents to managing the metrics and data that have traditionally been embedded across documents stored in separate systems created by quality, manufacturing, operations and design teams.

Making a shift to operational excellence

Medical device companies can improve their ability to pursue operational excellence by digitally simulating scenarios in advance. Planning for manufacturing diversification can benefit from simulating material and manufacturing operations workflows as well as quality control operations to plan for optimized production efficiency. This allows teams to identify and work out quality problems virtually before real production begins.

A leading medical device company has standardized operational excellence solutions globally and improved the agility of their manufacturing operations by simplifying their quality systems. This has resulted in 78 percent fewer U.S. Food and Drug Administration (FDA) 483s per inspection versus the industry norm.

Centralizing modeling and simulation

Leveraging simulations of the manufacturing process can expand scenario planning. This can help improve the flexibility and speed of manufacturing medical devices for a range of markets and product configurations and improve surge manufacturing capabilities during a health crisis or sudden increase in demand. A centralized, globally available manufacturing modeling and simulation platform could use digital technologies to combine global standardization of processes with local and specific customization across multiple plants and acquired companies. This can also be shared with supply chain partners to support data exchange and change control process integration. This can help allow line changes quickly across all factories with low cost, speed and minimal production disruption since it removes the manual overhead and risk of error when sharing production specifications across teams.

While leveraging simulations of the plant floor and processes, you can also perform virtual commissioning. By easily creating a virtual environment, tests can be run long before the real system is built. Or in existing lines, tests can be run without disturbing the daily production and respective implications. This reduces commissioning times and costs while improving efficiency.

Contextualizing production data

The process of gathering, standardizing and contextualizing real-time manufacturing data across all participants in the supply chain can enable automated validation of production equipment and processes as well as improve the understanding of production quality that can be linked to other tools to improve and control manufacturing operations. Data can then provide feedback to the design and engineering departments to improve product quality. Eliminating manual DHR activities will improve resource utilization and remove errors. This contextualized data can help operations teams drive toward closed-loop manufacturing to lower costs while ensuring product performance.

Achieving operational excellence requires a cultural shift in how data is shared across medical device organizations. Improving the underlying infrastructure can simplify this transition. A big part of this lies in removing the focus on managing documents to contextualizing the data used to automatically generate documents. This shift will improve agility, produce consistent product quality and factory efficiency while still ensuring safety and compliance as you're able to adjust to the environment and stay innovative and competitive in the medical device market.

Conclusion

A digital approach to manufacturing with the re-use of a production digital twin to simulate, schedule and execute production, enforcing routes, quality inspections, rework and yielding quality-controlled devices and a perfect eDHR leads to operational excellence in the medical device industry.

About Siemens Operational Excellence for Medical Devices

Siemens Operational Excellence for Medical Devices enables operational agility, with real-time visibility, control and speed throughout the manufacturing process. It leads to high-quality, efficient medical device production that is regulatory compliant and provides perfect eDHRs.

Our solutions help companies of all sizes leverage digital systems to produce innovations that meet tomorrow's challenges.

For more information on Siemens Operational Excellence for Medical Devices, visit **siemens.com/OEMD** or follow us on LinkedIn and Twitter.

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