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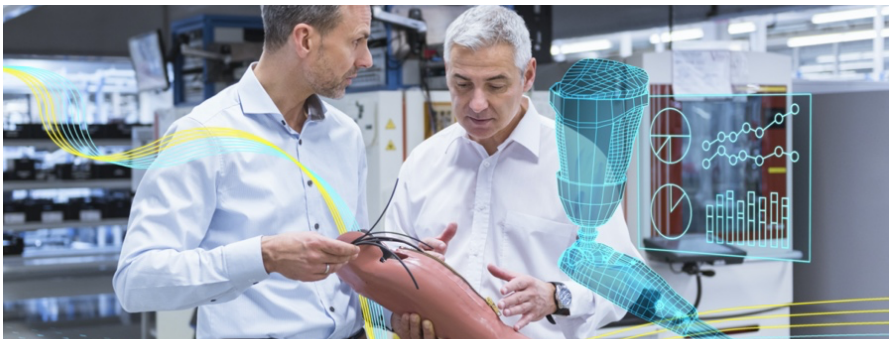
Operational Excellence

Charting a path to operational excellence with a focus on manufacturing

Medical device manufacturers have traditionally used paper-based methods to guide and track the execution of manufacturing processes, including creation of paper Device History Records (DHR). Industry leaders have evolved and implemented systems to automate manufacturing execution and the management of manufacturing data related to manufacturing processes, as an electronic DHR. Others have not yet evolved and are still using paper-based processes. But now, they are all starting to face challenges in scaling these systems, especially across globally distributed production facilities and when contracting with manufacturing partners.



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 types such as primary validation plans, pilot reports, and control plans, whether that be physically or the digital equivalent.

Medical device companies have begun adopting better tools for automating 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 through analytics or simulation to optimize manufacturing have 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.

Increasing Design Complexity

While their current processes, may satisfy their needs today despite their 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 (electronic Device History Record) 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 health care delivery providers. As seen in a recent executive order mandating essential medicines, medical countermeasures, and critical inputs be manufactured in the U.S. Those failing to plan for supply chain disruption will not be able to respond to changing conditions, as the recent shortages in critical medical equipment has proven.

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

In view of these challenges, companies will face extreme scalability challenges around transferring personalized, patient-specific design elements between product engineering teams, manufacturing engineering teams and operations teams and their collaborators within 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 on operational excellence solutions globally, and improved their agility of their manufacturing operations by simplifying their quality systems. This has resulted in 78% fewer FDA 483s per inspection versus the industry norm.

Reframing Design Transfer

Design transfer as a regulatory requirement has often focused an organization on meeting the regulatory burden through documented processes & evidence, with limited attention paid to the spirit of the requirement itself. 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 through 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 for compliance and safety, while improving supplier collaboration related to product data, design changes and quality controls.

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.

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 which can be linked to other tools to improve and control manufacturing operations. Data can then provide feedback to design and engineering department to improve product quality. Eliminating manual DHR activities will improve resource utilization and remove errors. This contextualized data can help operations teams to drive towards 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.

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