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Taking cost out of MedTech manufacturing and quality operations

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Introduction

MedTech manufacturing is demanding enough, but new challenges—and challengers—face the industry today that make bringing products to market more difficult than ever before. In fact, when considering the way most MedTech manufacturers operate, the process is arduous and extensive: Develop a new product that improves human health; wade through months or even years of clinical studies and regulatory approvals to ensure safety and efficacy; launch it to multiple markets all at different times as quickly as possible; and spend years improving the manufacturability of the design to ensure that the product finally achieves the financial benefits it was expected to.

The MedTech landscape has clearly shifted significantly over the past decade or so. The steady stream of high margins that many medical device companies have enjoyed is dwindling, given that margin pressures are more present than ever. Increased competition inside and outside the industry, shifting and inconsistent demand, and inflation create a perfect storm that is affecting the industry.

The growth of MedTech companies will be fueled by bringing new products to market more quickly and effectively. In parallel, new technologies will drive advancements in the smart factory environment necessary to accelerate product time to market.

In a smart factory, the entire production process leverages robotics, data analytics, distributed ledgers, augmented and virtual reality, artificial intelligence (AI), and the Internet of Things (IoT). These technologies connect operations, and in real time, support critical decision-making as part of the manufacturing process. Generative AI is also starting to affect the smart factory and drive value at an unprecedented rate.

MedTech manufacturers must therefore take steps today to prepare for what's to come by focusing on operational costs associated with labor, products, and overhead; and examining operational efficiencies, increased capacity optimization, and targeted cost takeouts.

Why now?

A variety of factors increase pressure on manufacturers, driving them to examine their operational costs. Overall, inflation and higher interest rates are financially affecting hospitals and other health care facilities more than ever before. Because of this financial strain, medical device manufacturers are feeling the weight of increasing price pressure. This spending reduction has led to challenges in balancing labor and demand.

Financial pressures also force CEOs to prioritize cost and asset optimization to regain some of their previously robust margins. This requires companies to place the design process and overall manufacturing and quality cost under a microscope.
Beyond these factors, several other elements can have an impact on operations. For one, there are more entry points into the medical device market. Companies previously specialized in a single type of device or therapy and established themselves as a leading manufacturer in that single area.

Today, MedTech is competing with "Big Tech," which is developing a rapidly growing market for consumer health products (e.g., wearable technologies that monitor heart rate fluctuations, sleep cycles, breathing patterns, and other health indicators). With Big Tech's ability to create and quickly deliver these multifaceted products to market, non-incumbents are finding and capitalizing on targets of opportunity, picking up MedTech customers along the way.

In response, incumbents must pivot their product design and development strategies to encompass a wider variety of medical devices (e.g., wearables, combo devices) than their business as usual, while addressing cost pressures on their legacy businesses.

Incumbents must respond in kind to Big Tech companies that are positioning their solutions as prevention rather than treatment. Finally, it is also critical that MedTech companies work to bring such devices to market more quickly and do so by meeting volume and cost requirements—which is where manufacturing comes in.

Operational efficiencies

Employing lean manufacturing methods, MedTech companies have made significant strides toward higher operational efficiency. However, recent manufacturing improvements have provided more opportunities for cost reduction on all fronts. This can ultimately lead to more efficient workflow, less bottlenecking, increased outputs, and lower cost of goods sold.

Key examples of these advances include the end-to-end digitization of supply chains, sensorization of devices, and improvements in tracking technology, leveraging intelligent automation (IA) and Generative AI throughout manufacturing and quality operations, among others.

Advancements in cloud and the volume of data being generated are making AI more accessible as a tool to understand operations and drive efficiencies throughout MedTech manufacturing and quality operations. As a result, this could facilitate a more detailed understanding of specific product inputs, the ability to highlight points of product improvements, and a better ability to manage tolerances.

Additionally, implementing no-touch manufacturing execution systems through sensors, can help reduce the dependency on highly experienced operators through 3D work instructions and smart-sensing quality checks on the work being done. These elements are vital to reducing costs in MedTech manufacturing and could also help manufacturers discover differentiated capabilities and reduce preventable anomalies while increasing the consistency of production—a win-win-win for MedTech manufacturers.

Overhead and capacity

Oppressive overhead costs in manufacturing and quality operations cannot entirely be attributed to meeting specific quality management system (QMS) standards—though, meeting these standards is certainly one significant driver of operating costs in MedTech. MedTech companies often fail to reevaluate operations and efforts surrounding quality on a periodic basis. Compliance is required, but a continuous focus on reducing or eliminating non-value-added activities can shave significant fixed cost.

MedTech companies that reevaluate their quality systems and operations regularly can identify new cost reduction levers to pull while maintaining, if not improving, the quality of their operations.

Many companies that have successfully worked toward lean manufacturing are shifting to a more deliberate and meaningful approach. For example, instead of merely satisfying requirements as before, some organizations are rethinking the role of quality in the organization and making it a key driver of business outcomes and a key partner to the business. This often requires new ways of working, thinking about quality, and operating with business partners to drive value to the organization—with common and aligned goals and measures of success.

It should go without saying that you cannot inspect quality into a product; instead, quality emerges from material consistency, efficient and consistent production, and streamlined processes. Companies that reduce overall manufacturing and quality costs can pay greater attention to manufacturing plant capacity and focus on improving throughput within the four walls of the plant.

When facing capacity constraints and capacity pressures, optimizing the functionality of an existing space is often a more viable option than building a new manufacturing plant. And working to understand your plant and get more out of it will naturally lead to clear opportunities for cost reduction in existing operations.

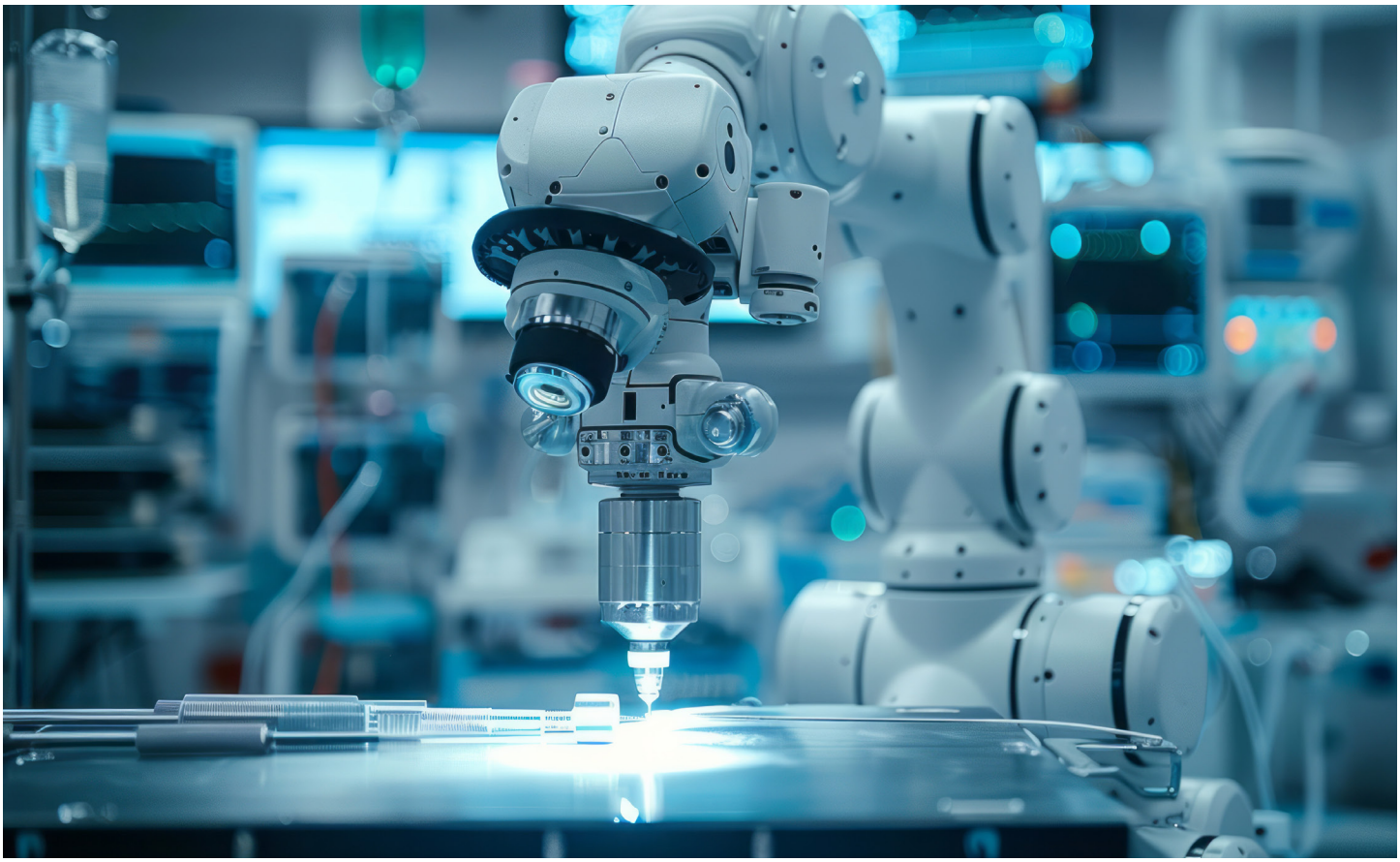
Optimization takes many forms, including outfitting a facility with more energy-efficient measures to increase sustainability. For example, shifting to clean energy by installing a solar power system on the facility's roof contributes to environmental conservation and reduces energy costs—potentially yielding green public relations wins as well.

Final thoughts

MedTech companies must make operational changes for the present while preparing for a more resilient future. Now is the time to start initiating changes to make strides toward operations efficiency and the smart factory or else risk losing ground as other companies pivot their approaches.

Today's environment and the general direction the industry is trending are leading companies to focus on cost takeout for manufacturing. But they must move beyond lean to focus instead on smart factory and incorporate AI in manufacturing. In doing so, this can shift traditional QMS away from something that must be accomplished at cost to something that can enable cost takeout.

By scrutinizing operational efficiency and collecting more robust data, companies can develop smarter capabilities that feed into product design from inception, initially paving the way for lean manufacturing and, ultimately, enabling AI-equipped Smart Factories. In turn, they can design even more cost-effective devices, alleviating financial strain while addressing demand—and returning margins to where they should be.



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