WHITE PAPER

BREAKTHROUGH MEDTECH

Headwinds, Tailwinds and the Flight Path to Success

molex

Despite economic uncertainties from the 2020 pandemic, the medical technology industry (MedTech) is expected to enjoy healthy future growth—as much as $432 billion globally by 2025.[1]

The positive numbers are fueled by digital transformation and an aging demographic; in the United States, national health expenditures will hit nearly 20% within the next decade.[2] Emerging economies across Asia, Europe and Africa are also opening up new avenues for growth.

Within the industry, connected medical devices enjoy the unique power to deliver volumes of data that can transform patient care and demonstrate value to payors (namely Medicare and private insurance). So it's no surprise that the connected device segment alone may grow nearly 25% by 2024.[3]

However, with continued mergers and acquisitions activity, disruption and regulation—to say nothing of the global pandemic—taking advantage of the opportunities will be challenging for even the smartest players.

A SIGN OF GROWTH:

18%

MedTech shareholder return, 2011-2016

(S&P 500 average: 15%)[4]

Breakthrough connectivity from a device's underlying electronics, and the industry expertise of those providers, offers a promising route to success and the best way to transcend commoditized offerings.

INDUSTRY TRENDS:
WHY CONNECTIVITY IS KING

Many of the most influential trends shaping the MedTech industry are related to connectivity and a product's ability to communicate with other devices and systems while quickly transferring large amounts of data.

INTEROPERABILITY

There's a reason consumer technology giants such as Apple are aggressively entering the MedTech market. The Apple Watch, for example, features a single lead ECG that can detect and alert you to abnormal heart rhythms that increase heart attack risk. Smartphones may not have highly advanced artificial intelligence (AI) capabilities yet, but they offer the connectivity and bundling of software and electronic hardware that supports an ongoing interoperability trend. Interoperability isn't optional: MedTech must integrate, exchange and optimize care across the patient journey, connecting delivery systems, devices, clinicians, care managers and even payors.

What works in data centers or transportation might create an advantage in healthcare.

DEVICE SIZE

Smartphones have reshaped expectations for how consumers, especially younger generations, want to interact with the world and receive information. The result? An enduring trend toward mobility and remote interaction that requires MedTech manufactures to consider not only interoperability but also size and portability. The market expects devices to be smaller, sleeker, faster and connected.

Today's smartphone is more capable than some of the medical instruments of just five years ago. Traditionally siloed medical device companies have been looking at other industries to benefit from cross-pollination. What works in data centers or transportation might create an advantage in healthcare. There's a convergence of technologies, and smaller form factors and connectivity are the common denominator.

PATIENT EMPOWERMENT AND TELEHEALTH

Because of these new expectations, and a need for better access, patient empowerment has emerged as another mega trend to consider. For manufacturers, this is about creating more advanced wearables but also offering remote diagnosis, surgical assistance and monitoring in ways that could revolutionize healthcare access. And here, too, connectivity and the components that enable it are key to staying ahead of the trend.

The dominant product categories in MedTech—in vitro diagnostic devices (IVDs, performed at home or the point of care), other diagnostics, therapeutics and connected health—all make care easier for patients. Payors are already expanding reimbursement for remote monitoring and following new rules due to the COVID-19 pandemic. In fact, a recent U.S. executive order includes a proposed Medicare model that incentivizes clinicians to offer in-home dialysis.[5]

20%

U.S. healthcare expenditures increase by 2030[2]

> "We're becoming more accepting that a doctor does not have to be physically present for a patient to participate in advanced healthcare," says Anthony Kalaijakis, a mechanical engineer and Strategic Medical Marketing Manager at Molex. "Whether you're talking about minimally invasive robotic surgery, wearables that don't feel like equipment or offering advanced diagnostics in a rural area, it's about empowering patients and meeting market demand for portability."

CONNECTIVITY AND ONGOING REGULATORY CHALLENGES

Connected MedTech devices raise specific privacy and security issues, on top of a host of regulations that can disrupt production timelines. Working with a trusted partner who understands the regulatory landscape is as critical to product development as design, components and manufacturing.

THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA has temporarily relaxed some MedTech regulations to help hospitals manage the COVID-19 pandemic. However, the agency is well known for the lengthy, complex approvals process intended to protect patients and public health. While the process can serve as a barrier to entry, effectively limiting competition, it can also slow innovation. Even the FDA's newer Breakthrough Devices Program, intended to speed launch of lifesaving technology, presents manufacturers with a high bar for "breakthrough" qualification, as well as numerous other requirements for quality, security and privacy.

"Electronics have allowed my phone to talk to my insulin pump, which leverages my phone's cellular capability to tell my doctor that I've hit a low insulin level six times in the last four days and I might need extra care," says Austin Nicholsen, a mechanical engineer and Sales Manager at Molex. "This type of connectivity is closely tied to HIPPA privacy rules for FDA-regulated devices. You're going to see more young healthcare companies and consumer tech companies get into the field and try to navigate these issues."

AFFORDABLE CARE ACT (ACA, OR OBAMACARE)

The passage of the ACA brought an additional layer of scrutiny to the MedTech industry by putting more overall emphasis on safety, cost and performance. The good news is that the ACA favors personal diagnostics and monitoring, preventative healthcare, medication maintenance, infection control and therapeutic devices over lower-end commodity segments.[6]

The ACA favors connectivity-intensive personal diagnostics over lower-end commodity segments.

But health systems, one of MedTech's largest markets, are now required to improve quality of care and cost efficiency (i.e., value-based case) under new pay-for-performance fee structures. The effectiveness and reliability of healthcare devices and systems—critical for meeting these quality standards—rely on the robust design, engineering and performance of their internal electronic components.

It's worth noting that while the ACA has been under assault by the current administration, this may change as the need for a healthcare safety net becomes more pronounced. MedTech manufacturers will always need to account for the ACA as it evolves.

> "From diagnosis to applying the therapy and monitoring it, you've got to prove that your device actually works and is cost-effective," says Kalaijakis. "You've also got to be more nimble and global to manage different sets of regulations. These factors will define the next decade of med device regulation."

THRIVING IN THE MEDTECH MARKET

MedTech is a good place to be for technology companies—if they can capitalize on broader industry trends while navigating regulations. Choosing the right components provider for items such as cable assemblies, which can ensure exceptional connectivity, is a good place to start.

Key factors to consider in a provider:

CUSTOMIZES CABLE ASSEMBLIES

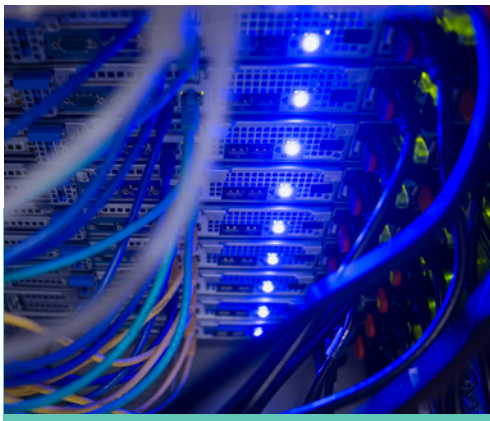
Beyond the benefits of off-the-shelf cables, customized cable assembles or modified off-the-shelf products can serve as a differentiating market strategy in a sea of commoditized devices and even reduce liability risk. Customization can also address specific regulatory concerns and speed the approval process.

"There's a lot of opportunity in this market space, but it's also daunting because many devices are similar and acquisitions are expanding portfolios," says Nicholsen. "You really have to focus on and customize the underlying electronics. And we're also seeing that, for example, what if someone inserts a cable into a USB and it fails? Many of our customers customize to mitigate risk while gaining a competitive edge."

LEVERAGES CROSS-INDUSTRY EXPERTISE

As other industrial and consumer electronic solutions converge into MedTech, keeping up will require a deep familiarity with a range of markets and applications. Choose a cable assembly provider with expertise in more than just MedTech and develops electronic solutions for diverse industries like transportation, IT, data centers, home appliances, mobile devices or others. This can help manufacturers rapidly tap into cross-industry insights, advances and problem solving that might otherwise take years to discover.

> "You always want to look for a breadth of capabilities across industries," says Kalaijakis. "We work with more than 20 industries that all rely on innovative electronic solutions. We happily beg, borrow and steal insights from each other internally to address MedTech customers' unique market challenges."



CUSTOM CABLE ASSEMBLY

Many customers customize to mitigate risk while gaining a competitive edge.

APPLIES REGULATORY KNOW-HOW

Given the lengthy and complex FDA approval process, and ongoing changes to regulations in Europe and Asia, manufacturers should consider regulation early on in development. The right suppliers and consultants can help navigate broad language around efficacy and safety, the expansive timeline and other testing and documentation requirements.

"Your suppliers and providers should be able to identify any area that might be a problem for approval," says Kalaijakis. "For example, if we have a customer who wants to put dissimilar materials together, we need to let them know that the combination could cause galvanic corrosion, leading to a device short circuit and risk to the patient. Standards like IEC-6061 and ISO-14971 offer good practices and risk assessment."

ENSURES A STRONG, COMPLIANT SUPPLY CHAIN

FDA approval and oversight now extends into the supply chain, and manufacturers have been forced to gain additional visibility into the quality of the supplier's product, supplier selection, communication and documentation. As supply chain logistics become more complex, manufacturers depend more on suppliers, designers and consultants —and these resources must stand up to rigorous quality standards and audits.

Suppliers should also have processes in place to ensure uninterrupted supply during geopolitical and natural disasters. The novel coronavirus is an example of how fragile far-flung supply chains can be and the potentially disastrous consequences of disruption. There should be a clear contingency plan for how to get essential tools and know-how to another facility in a timely manner without taking down the entire production line.

FDA SEC. 820.50

Shifts the burden of supplier regulatory compliance to the manufacturer. They must choose only suppliers and consultants who can provide quality products.

CONCLUSION

Despite steep regulatory hurdles, intense acquisitions activity and ongoing disruption, MedTech growth will continue to be strong. Molex can help customers navigate this landscape successfully. We work closely with our customers to find the right custom cable assemblies and other electronic solutions that make innovative design possible in diagnostic imaging, therapeutic and surgical, patient monitoring, hospital and patient care and healthcare IT applications. We apply deep regulatory experience and cross-industry expertise and leverage a network of distributors, specialty manufacturers and design specialists. Together, we can build a world of innovation, creating lifesaving connections between doctors and patients while ensuring success for our MedTech manufacturing partners.

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