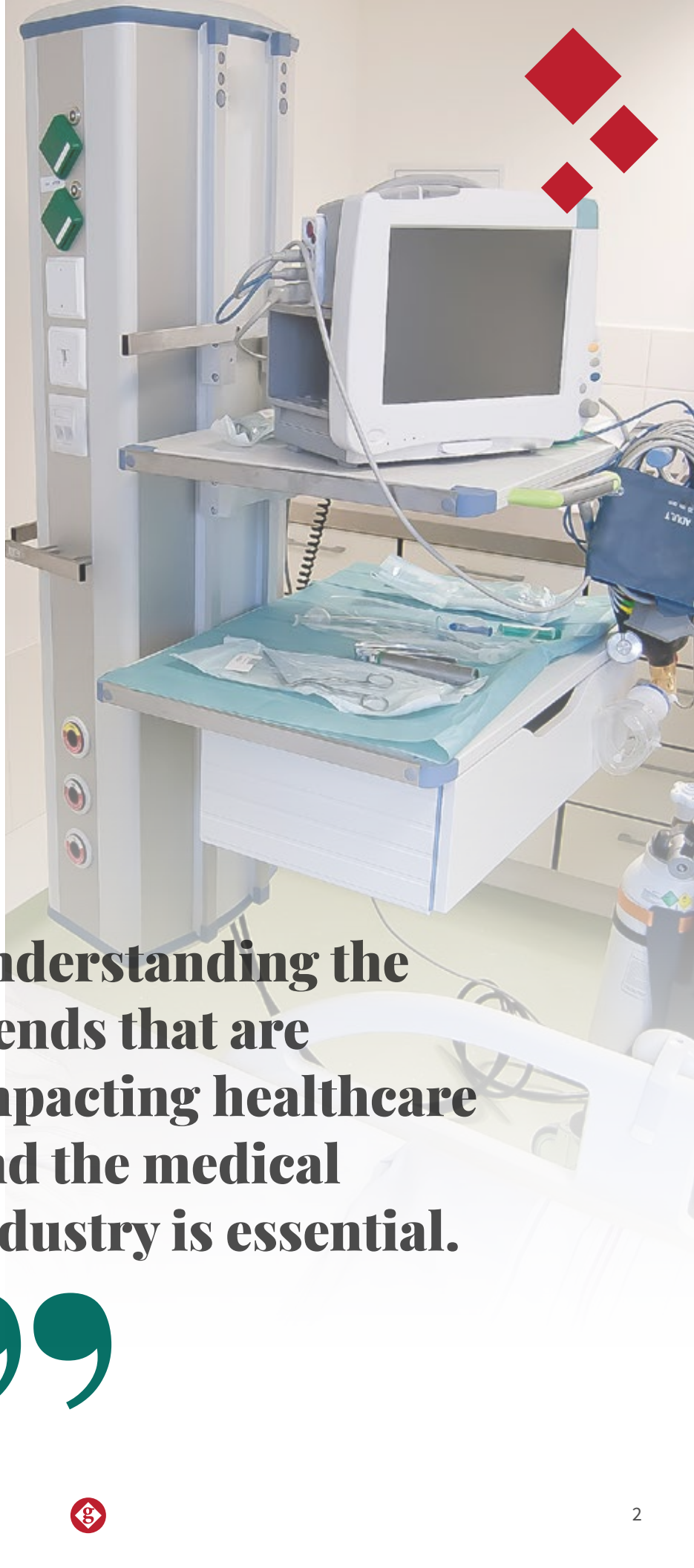
Medical Device Manufacturing

TRENDS FOR 2020

Advancements in healthcare are rapid and increasingly complex. **Medical OEMs are challenged with providing solutions that keep pace with the industry and, ideally, outpace the competition in the marketplace.**

Contract manufacturing partners play an important role in how well OEMs are able to meet critical needs. To that end, understanding the trends that are impacting healthcare and the medical industry is essential. They provide insight, direction, and clarity that contract manufacturers can use to guide decision making and collaboration with their medical OEM partners.



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What's Happening in Healthcare?

Having a grasp of larger initiatives currently underway in healthcare puts the evolution of medical devices and equipment into context. Here are a few of the more prevalent trends shaping the medical industry:

Minimally Invasive Procedures

Medical advancements that benefit both patient and doctor are coming to the fore through next-gen technologies and device miniaturization. Managing the size of the device equates to managing the amount of time and potential risk involved in surgery, and also reduces patient recovery time. Minimally invasive devices are generating so much interest, in fact, that the market is projected to grow at a compound annual growth rate (CAGR) of 8% by 2024.[1, 2]

Embedded Software

Some of the systems and tools of the medical profession are transitioning from Cloud-based software and external networks to embedded software. This presents some challenges inasmuch as troubleshooting, risk management, and cybersecurity — not to mention additional training for medical professionals. There is also greater need for design control and testing since embedded software/ firmware could introduce defects that aren't necessarily readily detectable.

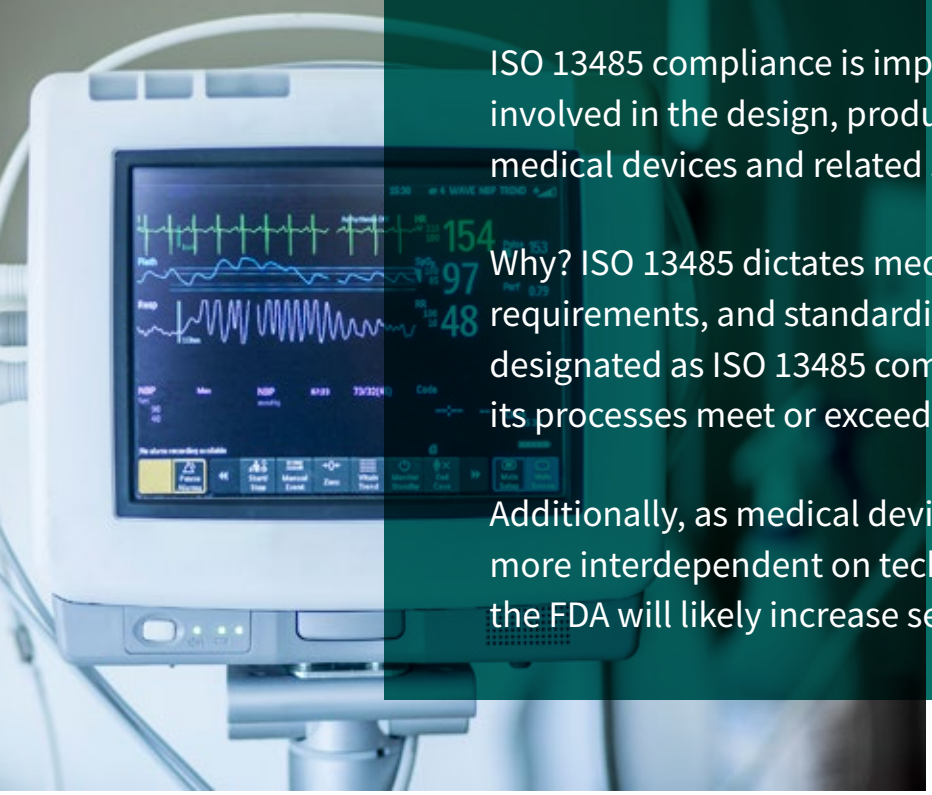
Wearable Technology and Smart Devices

Wearable devices are mainstays. Forecasters estimate sales of personal, connected gadgets to easily top one billion by 2022.[3] Because of the wealth of custom, highly personalized data and monitoring available through devices like smartwatches, patients influence the customer experience now more than ever. The medical field is taking notice and is tailoring interactions around wearables and smart devices.

Stricter (But More Expedient) Classifications

Medical devices and equipment are relied upon in every aspect of healthcare — from the operating room to patient monitoring and examination. It's not surprising, then, that the FDA and regulatory agencies are clamping down on the devices, the applications/interfaces used with them, and mobile accessibility.

Classifications for medical devices — like 510(k) and PMA scientific and regulatory review of Class III medical device safety — are popular, but are also being usurped in some cases by the streamlined De Novo process. This pathway essentially classifies medical devices based on controls and reasonable assurance of safety and effectiveness for the intended use. De Novo is a risk-based classification process since it isn't linked to legally marketed predicate devices.[4]



Classification Isn't Compliance

ISO 13485 compliance is imperative for any OEM or supplier involved in the design, production, installation, and servicing of medical devices and related services.

Why? ISO 13485 dictates medical device quality and safety requirements, and standardizes them for worldwide use. An entity designated as ISO 13485 compliant holds unequivocal proof that its processes meet or exceed medical industry needs.

Additionally, as medical devices become more sophisticated and more interdependent on technologies and/or advanced software, the FDA will likely increase separate compliance initiatives.[2]

The Changing Role of Contract Manufacturers

Medical OEMs are becoming more selective about their contract manufacturing partners, with good reason. The complexities and functionalities required of suppliers has only ratcheted up in proportion to need within the medical industry.

The value-add of contract manufacturers is evidencing itself in support capabilities that include supply chain management, conceptual design and development, granular testing, and specialized processes and production.

Not every contract manufacturer is able to provide broad-based support, but those who do are integral to helping medical OEMs move forward. Productivity and efficiencies improve, time to market is quicker, and products are of consistent, high-quality.

As the trends suggest, medical OEMs must manage substantial and ongoing changes. Contract manufacturers like GMI Solutions that can come alongside to guide testing, strengthen processes, and ensure ISO 13485 compliance to support successful outcomes is increasingly necessary. We are proven in medical applications and dedicated to being a true partner to you.

Contact GMI today to discuss where the medical industry is headed and how we can help you lead the way.

SOURCES

[1]MPO-mag, Top 10 Trends In The Medical Device And Equipment Industry
[2]MPO-mag, 6 Trends Reshaping Medical Equipment Manufacturing
[3]Statistica, Global connected wearable devices 2016-2022
[4]FDA, De Novo Classification Request, Undated

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