

New Medical Device Manufacturers Require Expert Climate Control Solutions



Digital technology is transforming the world, and healthcare is no exception. With a growing number of medical devices connecting to the Internet of Things, an increasingly complex digital health ecosystem has begun to flourish.

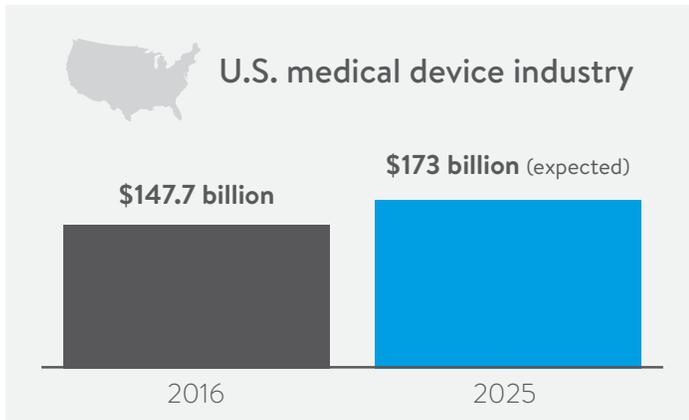
Insulin pumps communicate with glucose monitors and use algorithms to determine dosages. Ingestible sensors monitor drug levels in the system and transmit the data to a mobile app. Medical device manufacturers are harnessing the power of artificial intelligence to make devices more powerful and effective.

“As medical device manufacturers collaborate with electronics, sensors and IT companies to create sophisticated medical products, the latter also are recognizing healthcare as an important application

for their technology platforms,” says industry analyst Bhargav Rajan. “Emerging technologies have the potential to replace existing clinical practices, and make healthcare delivery more effective and affordable.”

More than 500 million patients are expected to use mobile healthcare apps this year, and eight in 10 industry CEOs believe medical devices will be fully digitized by 2020. As investments in the digital health sector grow by more than 40 percent a year, the pace of innovation is only going to increase.

“The medical device and imaging technology space is experiencing fast-paced research and development activity to meet the demand for cutting-edge technologies to cater to an aging population and a high number of patients suffering from chronic diseases,” says Frost & Sullivan’s TechVision team.



The U.S. medical device industry reached \$147.7 billion in 2016, accounting for more than 40 percent of the global market. With new technologies continuing to arise, it's expected to expand to \$173 billion within the next couple of years, achieving double-digit growth rates by 2025.

This rapid growth poses new difficulties for manufacturers, however, who must figure out how to stay on top of the changes while navigating a restrictive regulatory environment—something more than half of CEOs cite as their greatest challenge.

“Medical device companies are going through challenging times,” says tech firm HCL Technologies. “The mounting need to sustain the momentum of business growth and innovate amidst increasing regulations and competition is creating a lot of pressure on the topline as well as the bottom line.”

Ensuring medical device quality

To meet the demand for cutting-edge innovation, the medical device industry devotes a large chunk of its spending to research and development, averaging 6.7 percent of its revenue from 2011 to 2016. That's more than the automotive, defense and telecom industries pour into product innovation.

With so much invested in research and development, the ability to take products to market quickly and efficiently is crucial. But companies can't afford to sacrifice quality in the process. Medical device failures can cause disabling or life-threatening health complications for patients, and the cost of mistakes is high.

Increasingly stringent regulations on the medical devices millions of patients use every day demand strict quality control and regulatory compliance from manufacturers, whose products must undergo rigorous physical and chemical testing before they're approved for the market.

“Regulations for quality systems may cover the methods, facilities and controls used by the manufacturer in the design, manufacture, packaging, labeling, storage, installation, servicing and post-market handling of medical devices,” says the Food and Drug Administration. “Therefore, quality system requirements can influence all phases in the medical device life span.”

According to the FDA, more than half of all medical device recalls stem from failures in product design and manufacturing process control.

Yet many medical device companies lack the quality infrastructure needed to ensure high-quality manufacturing. As the pace of development and production grows, failures are becoming more common. In fact, serious adverse event reports related to medical devices have outpaced the industry's growth by 8 percent a year since 2001. According to the FDA, more than half of all medical device recalls stem from failures in product design and manufacturing process control.

The FDA states that, “Increasing complexity of medical devices and usage environments is straining the current quality system infrastructure.”





Climate control solutions for medical devices

Because so many of today's medical devices contain sensitive digital circuitry, environmental conditions can have a big impact on production quality. A cleanroom environment with a consistent atmosphere is crucial for medical device manufacturing—and humidity control plays a key role.

“Poor manufacturing management can produce inconsistency in the quality of products, such that non-conforming devices can filter through the production line to the market, even when the original prototype has been well-designed,” says the FDA.

Any change in moisture content can damage delicate electronics as well as other materials used in medical devices. Dangers run the gamut from condensation caused by high humidity to static discharge due to low humidity. Moisture levels may also need to be manipulated to activate certain chemicals or suppress dust and airborne particles.

Unfortunately, many manufacturers struggle to maintain the right environmental conditions for

sensitive medical devices. Standard HVAC systems in manufacturing facilities often aren't designed to create the precise conditions needed to ensure high-quality production.

As a result, “poor manufacturing management can produce inconsistency in the quality of products, such that non-conforming devices can filter through the production line to the market, even when the original prototype has been well-designed,” says the FDA.

Rather than replacing existing HVAC systems, many manufacturers rely on temporary climate control systems to create the necessary conditions. Through the use of dehumidifiers and other climate control solutions, medical device companies can maintain precise temperature and humidity levels throughout the manufacturing process.



With the right environmental controls in place, manufacturers can increase their production yield while reducing the likelihood of device failure. By improving efficiency and delivering better products to market, climate control solutions can help cutting-edge companies can stay on top of the competition.

The growing medical device market opens up exciting new possibilities for developers and manufacturers who are prepared to navigate its demanding regulatory and quality requirements. Will you be one of them?