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2015 OUTLOOK

Medical Devices 2015 Innovation Outlook

The medical devices industry continues to face significant pressure due to issues such as reducing healthcare delivery costs and transitioning to outcome-based reimbursements. Boston Engineering spotlights three trends shaping the medical devices industry in 2015 and beyond.

1) Capitalize on the Demand for Smart Devices.

Nearly half of the world's seven billion people have no access to medical care, and we can't build enough clinics or train enough physicians to solve this problem. The only way to deliver healthcare to remote corners of the globe and to underserved areas here in the U.S. is with remote diagnostics and therapies.

The Internet of Things (IoT) and associated wireless capabilities are providing a new framework to advance e-health and improve virtually every aspect of healthcare.

Wearable device technology is just one innovation that has significant healthcare applications. ABI Research estimates that 22 million wearable healthcare devices shipped in 2014 and projects this number will reach 34 million in 2015.

One notable IoT solution features a wearable heart monitor by start-up Infobionics that sends, stores, and analyzes patient data in the cloud. When Infobionics detects a cardiac event, it notifies a physician who first reviews the patient's ECG to make a diagnosis and then coordinates care quickly.

Using IoT and other technology advances, I envision primary care physicians (PCPs) making house calls again. Only now, I'll be talking with my physician via a Skype-like application or even have a conversation with a hologram of my doctor while he is checking my vitals using data transmitted from my wearable or implanted monitoring devices.

2) Address Shifts at the Food and Drug Administration (FDA).

Many venture capitalists say that they are not investing heavily in the medical devices industry due to a perceived high level of uncertainty surrounding FDA clearances. This concern is overblown and doesn't warrant the degree of pull-back in funding that we're seeing.

A company that submits its 510(k) for substantial review typically receives questions from the FDA within 30 or 90 days of accepting the document (for special or traditional submissions respectively). These questions may require additional testing, and in some cases, require a design or process change. However, the agency's questions and requirements are specific and are usually addressed in a relatively short amount of time.

As an example, we recently managed the clearance process of a Class II medical device, which took 130 days from beginning to end. This included submitting a traditional 510(k), holding a call with the FDA to clarify the agen-

cy's follow-up questions, providing written responses to the FDA, and receiving clearance.

An experienced medical devices team understands what's involved with the 510(k) process, will have anticipated and planned for this "extra" work, and will respond to the agency's questions quickly to minimize potential process delays.

Separately, the FDA has not been an obstacle to IoT and related wireless technologies reaching the market, which has been surprising to many in the industry (myself included). In fact, the agency should be congratulated for staying in front in this area and granting new clearances for these types of devices virtually every week.

3) Watch for the Repeal of the Medical Device Tax.

The medical device tax is ultimately a tax on consumers and is hindering our competitiveness internationally. The U.S. exports $44 billion of medical devices annually. During the past year, medical device exports grew less than 2% compared to more than 5% annually from 2008 to 2013. At the same time, device imports to the U.S. are increasing by almost 5% annually.

That said, I am optimistic that with the help of Congress, this downward trend can be reversed and the U.S. can continue its global leadership position in medical devices.

About Boston Engineering

Boston Engineering improves the way that people work and live through product innovation and novel engineering. We manage the entire product development process — from ideation to supply chain development. Certified for ISO 9001 and ISO 13485, our industry expertise includes consumer products, defense & security, medical devices, robotics, and industrial & commercial products. We are also the Northeast's largest PTC software reseller.

For the medical devices market, we combine innovative thinking with the technical and regulatory insights required for client success from the surgical suite to emerging models of patient care. Our medical devices product development process advantages include:

- Accelerating new product development
- Mitigating risk
- Cutting costs
- Complying to FDA and ISO requirements

Author

Dave Jacobs is the director of Boston Engineering's Medical Devices practice.

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boston-engineering.com
marketing@boston-engineering.com
781-466-8010