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MEDTECH OUTLOOK

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EXAMINING MEDICAL DEVICE DEVELOPMENT

By ***Steve Venditti,*** *Founder and CEO, Datum3D Product Development*

Current Landscape

Medical devices play an important role in the delivery of many health care services. Defined broadly, medical devices are items that are used for the “diagnosis…cure, mitigation, treatment or prevention of disease” and are not absorbed or metabolized by the body. The term applies to everything from common medical supplies such as latex gloves and syringes to advanced imaging equipment and implantable devices such as cardiac defibrillators. More recently, we’ve seen medical devices serve as extensions of a physician’s hands in surgery. The medical device industry is thus an important component of the larger health care system and plays an essential role by developing new medical technologies that can improve the ability to diagnose and treat illnesses or injuries. Recent studies by the Congressional Research Service (CRS) have estimated that the United States is the largest single market for medical devices and accounts for about 40 percent of worldwide sales. In addition, total U.S. spending on medical devices was $119 billion in 2011, $125 billion in 2013, and $172 billion in 2015 respectively. Medical device companies are located throughout the United States, but the industry has a larger presence in California, Massachusetts, and Minnesota.

Challenges and Opportunities

Medical device development companies are constantly trying to overcome design and manufacturing challenges to get their products in the market. While improving product quality and reducing manufacturing costs are always a concern, the FDA and ISO regulators can also present issues. Product compliance is a top priority for these firms who cannot go to market without approval from regulatory bodies. While industry regulations are warranted and likely to remain difficult, achieving regulatory compliance can sometimes restrict design creativity and development. However, with recent advancements in technology, some firms have been able to streamline their development process and create extremely unique products.

Steve Venditti

The medical device space is experiencing arising need for smart, automated and modular devices. The future of medical device development is in creating innovative products, integrating new technology, and overcoming regulatory constraints. Technological advances in computer-aided design, engineering, and manufacturing tools have allowed engineers to thoroughly innovate, analyze and verify each medical device component faster and with more precision than ever before. Medical device development firms are beginning to have more freedom and autonomy to express their creativity with new rapid prototyping equipment such as 3D printers, CNC machines, and laser cutting technology. These advancements have not only enabled firms to expedite the verification testing for regulatory agencies, but also create more cost efficient and functional products.

Recent examples of how far the medical device industry has advanced include robotic surgical instruments and tele-robotic remote surgical procedures. “We’re starting to see automated robotic surgical systems designed to perform various minimally invasive surgeries that covera wide spectrum of procedures,” says Steve Venditti, CEO of Datum3D Product Development. “We’re also seeing breakthroughs in telerobotic surgeries take place,” Mr. Venditti added.This technology will dramatically improve patient access for both elective and emergency surgical interventions. It allows surgical procedures to take place remotely and its success paves the way for large-scale operations providing reduced time to treatment and minimalvariability in operator skills and success rates.

Supply Chain Ecosystem &Efficiencies

The supply chain for medical device development companies and manufacturers is complex and diverse. There are many challenges including the selection and approval of FDA regulated raw materials, components as well as verified manufacturing processes/assembly techniques. In addition, supply availability, project logistics and ever shrinking product schedules create challenges that can be insurmountable if not planned for accordingly. A successful project plan, must account for all potential design, documentation and manufacturing contingencies. It should also include accurate forecasts for production schedules to maintain product availability and assure appropriate levels of inventory for the life of the product.

Outlook

To remain competitive, firms need to modernize and streamline their development processes and implement the latest advancements technology has to offer. In this growing medical device marketplace, development firms that stay on the cutting edge of technology will hold a significant advantage over other players in the space and continue to produce revolutionary products. MT