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Speaker eBook

Q&A with the speakers from the

American Medical Device Summit 2015

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INTRODUCTION

There is less than one month to the American Medical Device Summit 2015. With the event on the horizon, we took a moment to gather some of our key speakers and asked them to share their insights and opinions on the current state and future outlook of medical devices in the U.S.

We posed the following questions:

1. How would you describe the current landscape for medical devices in America?
2. What are some of the biggest challenges that companies are facing when bringing medical devices to market?
3. How can these challenges be overcome?
4. When it comes to medical device inception, development or commercialization, what is the one piece of advice you wish that someone had given you?

How would you describe the current landscape for medical devices in America?

It is a challenging time for medical devices because of significant changes in the healthcare environment. Cost containment is a high priority in all of healthcare and much of the innovation now focuses on creating efficiencies. In the past, the large majority of the innovation was focused on improving outcomes.

Laura S. Whitsitt | SVP, Research & Emerging Technologies, Advanced Surgical Devices Division | Smith & Nephew

The healthcare industry in America is undergoing massive transformation. consumerization, outcome based medicine and digitization are fostering changes across the spectrum of patients, clinicians and device manufacturers. Device manufacturers and hospitals are investing in technology as key differentiator in driving innovative and cost-effective solutions for patient outcomes.

Phani Bidarahalli | GM & Head, Global Practice | WIPRO

In terms of medical technologies, there have been significant advancements in the last few decades, however, only in few areas could one project a “Moore’s law” analog in our space. New technologies typically move forward into the clinical environment relatively slowly, probably due to quality, regulatory and clear value proposition challenges.

James Martucci | Director, Technology Assessment & Scouting | Baxter

The landscape for medical devices in the United States is changing rapidly, with an unprecedented intersection of political, economic and regulatory forces requiring manufacturers to be creative and agile in establishing and deploying business strategies.

Brian Cousins | VP, QARA, Surgical Respiratory Care | Hill-Rom

The landscape is great but demanding. There are still tremendous unmet needs that we can address. The difficulty is that the current environment demands more from us in terms of design rigor and economic effectiveness than ever before. Long gone are the days of “throw it against the wall and see what sticks.”

John Daley | Multi-Site VP, QA | Boston Scientific

What are some of the biggest challenges that companies are facing when bringing medical devices to market?

Regulatory, clinical and reimbursement requirements are increasing, which adds cost and time to the development process. Significant resources in quality and manufacturing engineering are required to address these new requirements. The need across the industry for people with these skillsets is much greater than the talent pool.

Laura S. Whitsitt | SVP, Research & Emerging Technologies, Advanced Surgical Devices Division | Smith & Nephew

Some of the biggest challenges that companies face include:

- Substantially differentiated clinical offerings
- Embracing new technologies around smart manufacturing, cloud, IoT, 3D printing and interoperability.
- Frugal innovation and time-to-market
- Growing regulatory burden across the world

Phani Bidarahalli | GM & Head, Global Practice | WIPRO

Key challenges being faced in bringing medical devices to market include uncertainty in reimbursement levels due to healthcare reform, the relatively slow pace of innovation caused by regulatory review, and global competition.

Brian Cousins | VP, QARA, Surgical Respiratory Care | Hill-Rom

In today's environment, we face three over-riding challenges in bringing medical devices to market: We must create value-based healthcare solutions; secondly we must deliver innovative, meaningful therapies and procedures to help our customers care for patients; and thirdly we must address the inequities in healthcare access across the globe. The cadence by which we solve these continuing challenges is what will define our success.

Robert Berger | VP, Contract Manufacturing | Medtronic

Key focus areas: reimbursement and value proposition, usability and risk management, delivering on critical to quality requirements.

James Martucci | Director, Technology Assessment & Scouting | Baxter

Given the size and maturity of the market, one of the biggest challenges is actually getting your devices noticed and having their value propositions understood by a broad audience. We can no longer just win a few key opinion leaders (KOLs) and use that to create market success. Now we must not only win those KOLs, we must win their hospital and buying group partners along with the regulators as well.

Another challenge is globalization. Whether it be for low-cost manufacturing or for market development, we need to realize that the entire globe is now the market.

John Daley | Multi-Site VP, QA | Boston Scientific

How can these challenges be overcome?

Programs such as rotational internships, can be put in place to provide a talent pool within the organization to develop these skill sets.

Laura S. Whitsitt | SVP, Research & Emerging Technologies, Advanced Surgical Devices Division | Smith & Nephew

Device manufacturers have to foster strategic and sustained partnerships to develop to overcome these challenges. With rising pressure on R&D spending, device manufacturers have to focus on their core offerings and leverage a broader eco-system to leapfrog in technology and digitization.

Phani Bidarahalli | GM & Head, Global Practice | WIPRO

Take time to perform a technology scan and objective assessment of available technologies to address customer needs.

James Martucci | Director, Technology Assessment & Scouting | Baxter

To overcome these obstacles, companies must invest early in processes which result in robust and reliable products as well as manufacturing processes. A key element of future success will be the avoidance of unplanned product changes.

Brian Cousins | VP, QARA, Surgical Respiratory Care | Hill-Rom

The elements which differentiate successful manufacturing sites from those that struggle are:

- The strength and depth of the junior leaders who execute the tactical decisions which ensure the safety of their teams and the quality, cost, and delivery of the product; all in compliance of the heavily regulated environment in which we work;
- The culture of accountability-to-the-patient in which individuals are readily recognized for good performance. This requires strong product awareness, effective communication and visible, meaningful metrics throughout the plant;
- Continuous Improvement at all levels within the plant. Complacency destroys value.

Robert Berger | VP, Contract Manufacturing | Medtronic

Everyone needs to realize that having a great product is not enough. You have to have a great company. This means product development, quality, regulatory, supply chain, marketing and sales all have to be working together to create a true value proposition for the customer.

John Daley | Multi-Site VP, QA | Boston Scientific

When it comes to medical device inception, development or commercialization, what is the one piece of advice you wish that someone had given you?

There are many things that influence the success of a product including ease of use, value, clinical results and product perception. You can have a product with excellent clinical results, but if a similar product has had clinical issues, it can taint the perception and success of your product. It is important to consider all factors that go into the decision making process when developing a product.

Laura S. Whitsitt | SVP, Research & Emerging Technologies, Advanced Surgical Devices Division | Smith & Nephew

In the inception phase, don't select and ramp up a development program until you are confident you have a technology that simultaneously meets technical, clinical and business needs.

James Martucci | Director, Technology Assessment & Scouting | Baxter

You are only as good as your process. If you don't have a good end-to-end process, your job is going to be much harder. Regardless of whether you are in product development, quality, regulatory, or anywhere else, spend time honing that process. Make it hum and your product (whatever it may be) will be the better for it.

John Daley | Multi-Site VP, QA | Boston Scientific

None, this is the greatest industry in the world and I am proud to be part of it.

Brian Cousins | VP, QARA, Surgical Respiratory Care | Hill-Rom

Integrate new insights into your processes and build a roadmap for seamless device design, development, manufacturing and commercialization at the

American Medical Device Summit 2015

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www.amdsummit.com