

## Medical Device Equipment Manufacturers: Overcoming Growth Challenges through Operational Excellence

The medical device industry can be credited with numerous examples of improving healthcare delivery and enhancing the quality of life for many patients. However, leading companies know that ongoing success requires a nimble ability to continually adapt to emerging technologies, onerous regulations and rising costs. Medical device companies are once again facing several challenges that are hindering sales and profit growth potential.

In the face of forces they cannot easily control – shifting markets, changing customer needs, shrinking investment in innovation, tighter regulations, and higher taxes – many OEMs are turning inward, addressing their own structural costs through improved operations. Often prompted by revised go-to-market strategies, this focus on operational excellence has the potential to further improve the companies' competitive positioning (ultimately by improving their products' price points), as well as freeing up resources to explore new strategies.

### Growth Challenges

We have observed four overarching growth challenges for medical device companies:

**1. Customers are focused on cost containment:** Hospitals are facing increased demand for their services at the same time as their costs to administer that healthcare continues to rise and the payer landscape continues to evolve. (In the 2014 *L.E.K.*

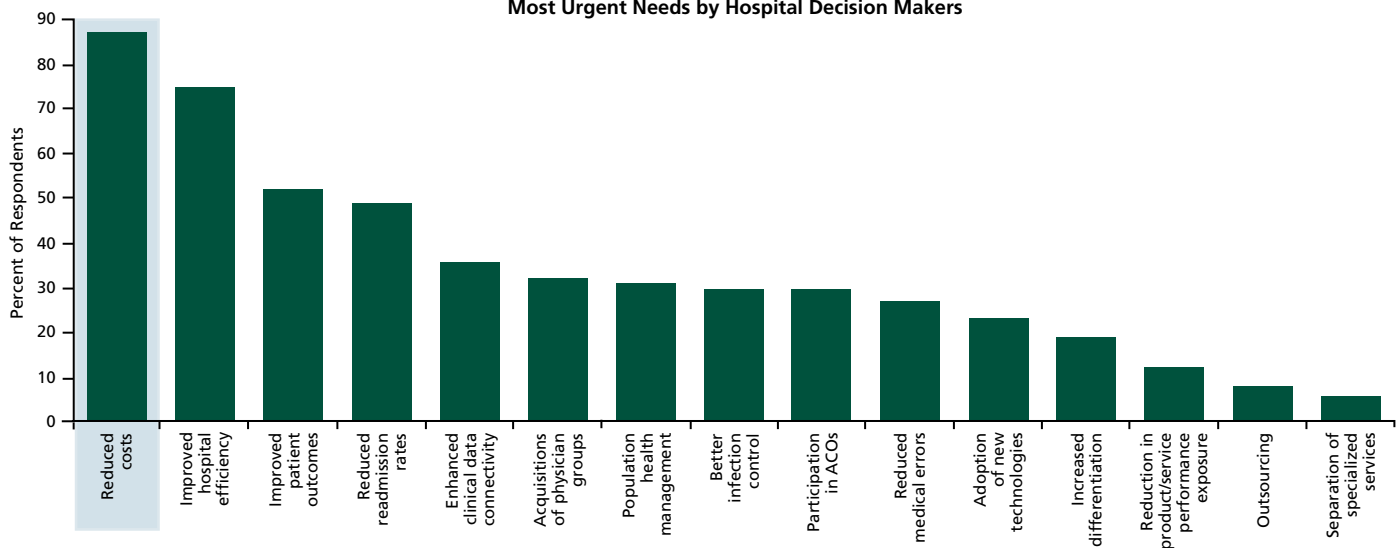
*Strategic Hospital Priorities Study*, 90% of the more than 150 hospital CEOs and senior decision makers surveyed claimed cost reduction as the most pressing need...) The result: more conservative and selective purchasing and focusing on solutions that can simultaneously improve patient outcomes and reduce provider costs (see Figure 1).

**2. The value of high-potential, emerging markets is tough to tap:** To make up for the slowing growth in their developed markets, medical device companies are, of course, looking at markets with more promising projected growth. But these regions are fraught with operational and commercialization challenges. For instance, the medical device market in China is expected to continue growing 25% annually through 2015. As with any of the Asian markets, success in China requires an OEM to manage tricky intellectual property (IP) protection, quality standards, and language and cultural barriers. Relying on Asian production facilities can further complicate logistics, increase shipping costs and slow the time-to-market.

**3. The hurdles for market approval are higher:** The European Union (EU) expects to finalize sweeping, more stringent changes to its medical device regulations later this year. The U.S. FDA has drafted plans for heightened post-market surveillance. China, one of the most promising markets, recently overhauled its rules to calibrate its scrutiny according to the risk a device presents. These universally stricter standards translate into higher development costs and slower time-to-market, a challenge

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**Figure 1**  
Most Urgent Needs by Hospital Decision Makers



Note: Currently, what are the most urgent needs in your hospital? Please select the five most urgent needs.  
Source: L.E.K. study

for all medical device companies, especially smaller, earlier-stage companies with limited resources.

**4. The innovation engine is slowing down:** Due in part to those tougher regulations, medical device companies are not realizing the same return on every R&D dollar invested. R&D spend for the top 20 medical device companies grew 7.4% annually between 2006 and 2012 but pre-market submissions to the FDA (510k's) actually declined by 1.2% during the same period. A slowing product innovation engine is taking its toll, at the same time as device makers are already bracing to absorb the impact of the Affordable Care Act's 2.3% excise tax on all U.S. sales of medical devices.

## Overcoming Challenges with Market-Savvy Operational Excellence

In response to these growth challenges, successful medical device companies are reconsidering how they bring new products to appropriate markets and raise the bar on operations to match. They differentiate themselves through operational excellence: refining their execution and optimizing the management of existing resources in order to maximize output, expand sales and improve profits (see Figure 2).

### Operation-savvy innovation and product development:

Between 50-75% of product costs are determined in the early phases of product design, as researchers and designers make critical choices in materials, manufacturing and sourcing. By injecting some operational reality early in the concept and design phases, companies can bring the products with lower final costs to market – a more competitive position with customers focused on cost containment.

To get this dose of reality, companies tap experts both within their organization – by including them on cross-functional design teams – as well as across their larger network of employees, suppliers and other partners. Suppliers, in particular, can contribute fresh ideas to lower manufacturing costs and identify new sources of product differentiation.

Medical device companies can learn from the best practices of other industries, as well. For example, Kraft Foods developed an open innovation program to tap into ideas and IP from inside Kraft, as well as its vast supplier and partner network. (Prior to implementing this open innovation concept, Kraft's IP portfolio amounted to a mere ~2% of the total patent portfolio of its suppliers and partners.) The new infrastructure of processes and systems – including the portal "InnovateWithKraft.com" – captured unsolicited innovations from potential suppliers, which the company used to develop new products, processes, packaging, ingredients, etc., across its snacks and grocery businesses.

**Figure 2**  
Mapping Operational Performance to Growth Challenges

		Growth Challenges			
		Increased customer focus on cost containment	Slowing growth in developed markets; need to capture value in emerging markets	Decreasing innovation	Increasingly stringent global regulatory environment
Operational Performance Levels	1 Innovation and product development	✓	✓	✓	
	2 Emerging market product development	✓	✓	✓	✓
	3 Visibility	✓	✓		✓
	4 Planning and forecasting	✓	✓	✓	
	5 Technology	✓	✓	✓	✓
	6 Contract manufacturing and right-shoring	✓	✓	✓	✓

Source: L.E.K. research, analysis and experience

**Adaptability in emerging markets:** Device OEMs are adapting the products they already sell in the U.S. and Europe to suit the new, emerging markets in Asia. Many companies are already manufacturing in these markets – originally motivated to move there by lower wage rates – but are now developing go-to-market strategies specific to the Asian markets' price sensitivity and regulatory requirements. Companies that can be more agile in adapting both their products and operations for these market strategies will control development costs and reduce the time to market, thus reaping more return on existing products, rather than starting from scratch.

For example, Covidien, a leading provider of healthcare products, approached emerging markets carefully. It laid groundwork first by investing \$45 million in its China Technology Center Research and Development facility in Shanghai, China. This Center will provide a focal point for collaborating with local medical experts in order to design products tailored to meet the needs of China and emerging Asian markets.

**Transparent supply chains:** Managing the multitude of suppliers, manufacturing locations, distribution points, carriers, etc. in a global supply chain is a daunting challenge. OEMs need visibility into supply sources far upstream in order to efficiently manage inventory and meet service levels.

Stryker, for example, improved coordination with its suppliers to reduce inventory investment and reduce the bullwhip effect. It adopted Tradebeam's iSupply solution and shared key production and inventory data with suppliers who could provide Stryker deeper visibility into inventory stocks along the supply chain. As a result, Stryker achieved a 30% reduction in material inventory for its manufacturing facilities, as well as a 30-40% reduction for its finished goods inventory.

**Advanced planning and forecasting:** In this era of slow growth, medical device companies are streamlining the cash-to-cash cycle by refining their planning and forecasting processes. Advanced planning and forecasting techniques and technologies help companies optimize their inventory investment while meeting sales goals.

GE Healthcare, for instance, focused on improving its sales and operations planning process in order to support increases in both sales growth and the number of SKUs in China. Alignment between sales, finance and supply chain teams has improved as have forecasts in accuracy and customer service levels.

**Tracking and tracing technology:** Companies continue to adopt RFID, bar-coding and other software solutions that integrate front-end ordering and customer service with fulfillment and distribution services. The technology offers greater potential than simply complying with FDA requirements for device identifiers. By tracking and tracing inventory and product,

leading companies are improving their service levels (and in turn improving satisfaction and sales), as well as reducing wasteful investments in inventory.

For instance, by shifting from manually intensive packaging to RFID-enhanced fulfillment, DePuy Orthopaedics reduced the time it took them to process orders for its replacement knee surgery sets from 30 minutes to less than one minute (all while maintaining 100% accuracy).

**Right-shoring:** Outsourcing is certainly not a new concept, but the nature of the risks – as well as the markets themselves – have changed considerably over the past decade, prompting leading manufacturers to reexamine the best combination of on- or off-shore, in-house or contract manufacturing.

Ten years ago, companies had to balance the cost benefit of outsourcing with real risks to product quality, as the products were mostly headed back to the U.S. or EU markets. Today, those quality risks are markedly lower and the available, reliable choices for manufacturing in any market far greater. Right-shoring is critical both to control costs for the developed markets

and expand into the markets where long-term growth is more promising.

For instance, the medical device market in China is expected to continue growing 20% annually through 2017. As with many Asian markets, device companies are increasingly manufacturing in Asia for Asia, turning to local, contract manufacturing partners and/or building new production facilities to support sales in the same region. There is no denying that successful manufacturing in Asia or any of the emerging markets requires a diligent initial selection – both of location and manufacturing partner. Equally important are the device makers' ability to maintain strong, ongoing relationships with local management teams and to continually re-assess the cost-benefit trade-offs of different sourcing options.

The growth challenges we have outlined are unlikely to abate any time soon. Improving operational excellence on multiple fronts – particularly when dovetailed with a refined go-to-market strategy – can help address these challenges more effectively and drive sustainable and profitable growth.

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