The US Medical Device Industry: future growth sectors may be different than you think.

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The medical industry is one of the most stable industries with respect to growth. However, we are seeing interesting global trends that will impact the sustainability of medical device manufacturers and suppliers across the United States.

With new changes occurring in the US healthcare, legal & regulatory systems, it's imperative that the US industry adapt in creative ways to expand profitability while still maintaining high product quality and compliance.

When you look at current, USA medical device sales, you can see an interesting trend; According to the World Medical Markets Fact Book, 2010, the five-year medical device CAGR (Compound Annual Growth Rate) in mature markets is estimated to be 7.5% vs. an emerging market CAGR of 15%. The markets in the United States, European Union, Canada and Japan are considered mature and extremely stable with relatively low annual growth rates. Emerging market countries with substantial populations, like China, India and Brazil are the main targets of direct foreign investment.

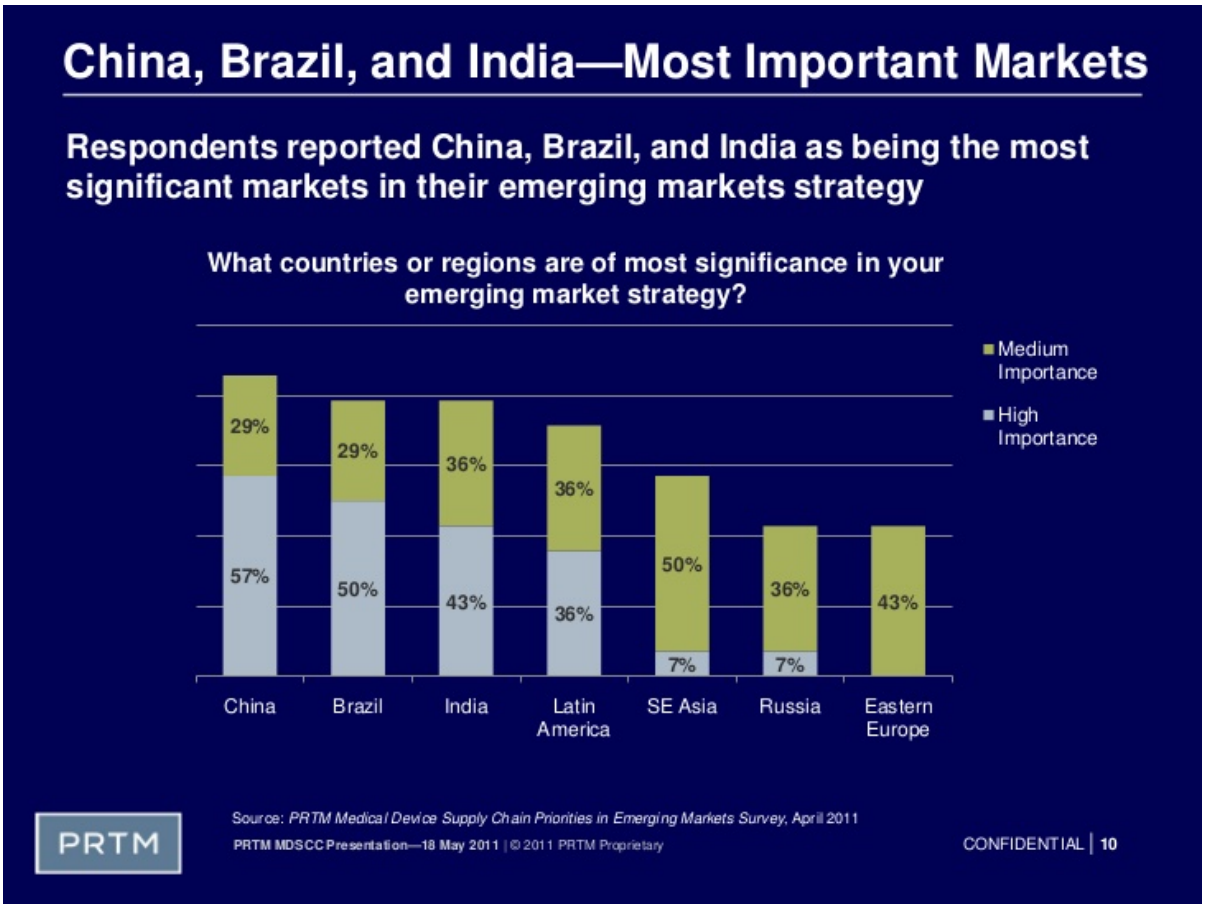

Image courtesy or PRTM management consultants

Based on these statistics, the thought process within the industry needs to change direction. Instead of trying to force sales in slow growth markets (USA, Canada, Japan), companies should focus on selling new versions of existing products to new, growing markets (China, India, Brazil).

"In a recent interview conducted by MD&DI with Sanjay Salunkhe, head of Global Business Development for Product & Engineering Solutions at iGATE;

Salunkhe claimed that the medical device market can be broken into three categories:

1. The premium market: the Western countries or the so-called "developed nations," which are willing to pay a premium for new technologies.
2. The second tier: this is a performance market where you are expected to provide more reliability and performance assurance for the product line.
3. The third market: which is the value market—the emerging markets. This is one of the largest areas for growth"

**Brian Muntz, MDDI Publication, September 15, 2012, "To Be Successful in Emerging Markets, Device Companies Must Embrace 'Bottom-Up Innovation'*

The strategic shift in thinking lies in the way a company is able to redesign their existing product lines to meet new market needs**. Recreate your device to offer value and reliability but use local resources to make your device**; the real benefit here is that you bypass the need to export your device into a foreign country. A company doesn't need to own or acquire manufacturing facilities. You just need to find those facilities with high end production and design capabilities.

Much like the automotive industry, outsourcing both administrative and technical / R&D assistance for medical device manufacturing is an inevitable step in the changing global industry.

Let's use China as an example for a "value market" emerging market strategy. The country already has an existing & reliable manufacturing infrastructure in place. A large number of factories are already FDA registered and ISO 13485 and GMP compliant. These facilities have the capability to make your products.

You should still continue to manage your foreign suppliers with regular FDA / ISO audits to ensure the GMPs are being followed & documented throughout your manufacturing processes. Just because you are making a lower cost product does not mean quality production should suffer.

Aside from quality issues, there are other country specific caveats one should be aware of.

1. Regulatory requirements should already be in place and approved before you even apply & register your device for sale. The China FDA (CFDA) will require documented evidence of your 510k clearance or PMA approval.

2. Prior to selling your products in China, you are required to assign a regulatory agent to your products & company to handle regulatory processing and maintenance. You should also acquire legal representation to manage complicated business issues in China.

3. Distribution in China is not a "one country" process. Each region has different specialties and hospital systems. You may need to partner with 3 or 4 distributors to be successful. This may also mean you need to have your products produced in 3 or 4 factories; ultimately requiring more manufacturing project management.

4. Your devices will most likely be purchased by patients paying out of pocket. The reimbursement system (the government) won't necessarily cover the cost of your device in question. For example, reimbursement for a hip replacement may only be covered at let's say, 50%. Then, the remaining payment due is out of pocket for the patient. The westernized system of health insurance does not operate in the same way within China. The upside here, since the culture has a growing middle class, more people are willing to spend income on higher cost health care products.

The opportunities are vast for new medical device sales across China and other Eastern, emerging economies. Important factors to keep in mind when introducing new products to foreign markets: give your company at least one year to prepare for adequate market sales. Assigning proper pricing, ensuring that regulatory requirements are met and choosing the right product type and distribution partners are essential.

Products to consider for sale in emerging economies:

China, India and Brazil:

Large markets with growing aging populations and access to technology are opening the doors to low cost, high value product sales.

- Home-use devices such as glucose monitors, insulin delivery devices, nebulizers and oxygen concentrators.
- Remote communication tech products allowing healthcare professionals to support home-based patients.
- Devices with solar power & battery backup capabilities to be used in remote and/or rural areas with limited power.
- Orthopedic implants promoting bone growth.
- Combination mechanical and drug devices. Prefilled syringes, drug eluding stents and implantable glucose pumps.

Medical Device companies of all sizes need to continue exploring opportunities for entering foreign sales markets. This shift is meant to offset the slower growth rates in the United States. The global market is the new “home market” for our medical products of the future. The market shift is necessary to survive in the long term. Regardless of where medical products are made and sold, regulatory and quality assurance parameters will always be required. Therefore, the objective of product development and sales should focus on making a product line with different iterations that will cater to a high end and 3rd tier market. Your company can stay in the same product space but cater to both slowing and growing markets.