

## Recent Market Trends are the New Market Reality

### TCG's Forecast for 2011 and Beyond

As we enter the New Year, this is a great time for all of us to look back on 2010. From this vantage point, it can be fun (or not) to see if the trends and events in the industry predicted last January actually came true. It is nice to know you were right --- or at least to know you were more right than someone else!

However, since TCG's goal is to create measurable value for the companies we work with, we will take this opportunity to focus on the trends that will affect you and your business in 2011-2012. As we do that, one overall theme we are compelled to note is an even sharper focus on de-risking the business enterprise. In fact, one could argue that this attitude represents a shift in thinking that will persevere for some time to come, given the uncertainty that remains in the global economy, and with health care and regulatory reforms.

In today's changing global medical market, the key questions have become "what's the opportunity?", and "how can we reduce our risk as we increase the value of our assets and grow our revenues and profits?"

As opposed to the past decade, when companies in our industry literally expected that customers would adopt virtually all new products, if enough money was thrown into marketing, the reality now is very different. For proof, we only need to look at the data:

- **Currency fluctuations** for the dollar and Euro are affecting the debt status of nations. As a result medical companies view multiple revenue sources from international markets as a proven way of de-risking the business. Even small to medium size companies in Europe are looking to US revenue sources, and vice versa.
- **Good economic policies** implemented by the more stable European countries are driving expansion into overseas markets. As an example, Germany's medtech exports grew by 5.5% last year and now represent 40% of total turnover. To de-risk their business, German manufacturers are developing US markets by picking and choosing selected customers and markets that generate attractive profits in the fastest way possible.
- **Government budget reductions** in Europe and the US are favoring cost effective innovation and new products that offset medical care costs. Before product development is complete, smart companies know which innovations will help them meet these goals, and then complete the product, marketing, and financing plans.

- **To increase flexibility and operations efficiency**, medical firms are down-sizing and out-sourcing manufacturing, R&D, and sales forces. In this environment, companies are doing more partnering deals and acquisitions of advanced and more proven products.
- **Emerging firms**, including US startup subsidiaries of established European companies, have increasingly moved to the virtual model to be more flexible and less capital intensive while launching products. While technical expertise is still a core competency, these virtual teams often include customer focused market and product development experts charged with ensuring the products will meet the market's true needs before major marketing dollars are committed.
- **Venture capital** remains scarce and the firms still investing are interested primarily in reducing risk, while the number of IPO's remains relatively low as well. This means that investors will be primarily focused on exits via acquisition, but this option won't exist unless the products or technologies are targeting a true, proven, customer need.
- **The EU Medical Device Directive** is increasing global harmonization and reducing regulatory risk even though it will increase the cost of regulatory approval for certain products. US companies launching first in Europe will increase in number, but the more informed executives have learned that Europe is not a unified market because of different reimbursement schemes in each country. They develop very specific, yet fully comprehensive European launch plans.
- **FDA changes in the 510K approval process**, along with proposed user fees, are galvanizing increased interest in launching first in Europe. This is also driving small to medium European medical companies to develop more thoughtful US market entry plans and commercial strategies. No longer do they view signing up with a distributor as some sort of guarantee of success.

The bottom line is that companies of all sizes are learning how to de-risk their business because of the world's economic conditions and because customers, patients, regulatory agencies and payors are demanding it. Companies can't assume that just because they have regulatory approval, and money for marketing, or have signed up a distributor in a new market they will be successful. Innovative companies have found that it is possible to increase both focus and flexibility --- two key risk reducers --- by leveraging outside experts to help commercialize their truly innovative products with proven cost effective marketing and sales plans.

*TCG LLC has the market experts with the experience and capabilities to help you survive and thrive in this new medical market. Call or contact us. [reinhard.merz@tcgmedtech.com](mailto:reinhard.merz@tcgmedtech.com) (Heidelberg, Germany) or [robert.keefer@tcgmedtech.com](mailto:robert.keefer@tcgmedtech.com) (Research Triangle Park, NC) or 919-941-0700.*

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## Upcoming Events

### Clinica Webinar

**March 1**

Join an online workshop on entering the US market from the global leader in Cambridge.

[Click here for more event info](#)

**Join TCG at industry and medical meetings in 2011**

We will be at 20 industry events in Europe and the US such as STS, EMT, ERBI and AACC.

[Click here for more event info](#)

**EuroMedtech**

*May 15-17*

*Turin, Italy*

Europe's largest medtech partnering conference, will include a TCG workshop.

[Click here for more event info](#)