

A snapshot of the medical device industry based on a survey of 2,600 professionals.

Conducted by:

EMERGO  GROUP

In cooperation with:

MedicalDeviceSummit
ADVANCING THE GLOBAL MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY

Executive Summary

Results of our 2012 medical device industry survey show that many companies performed well last year, but are also bracing for challenges and uncertainties in various markets in the coming year.

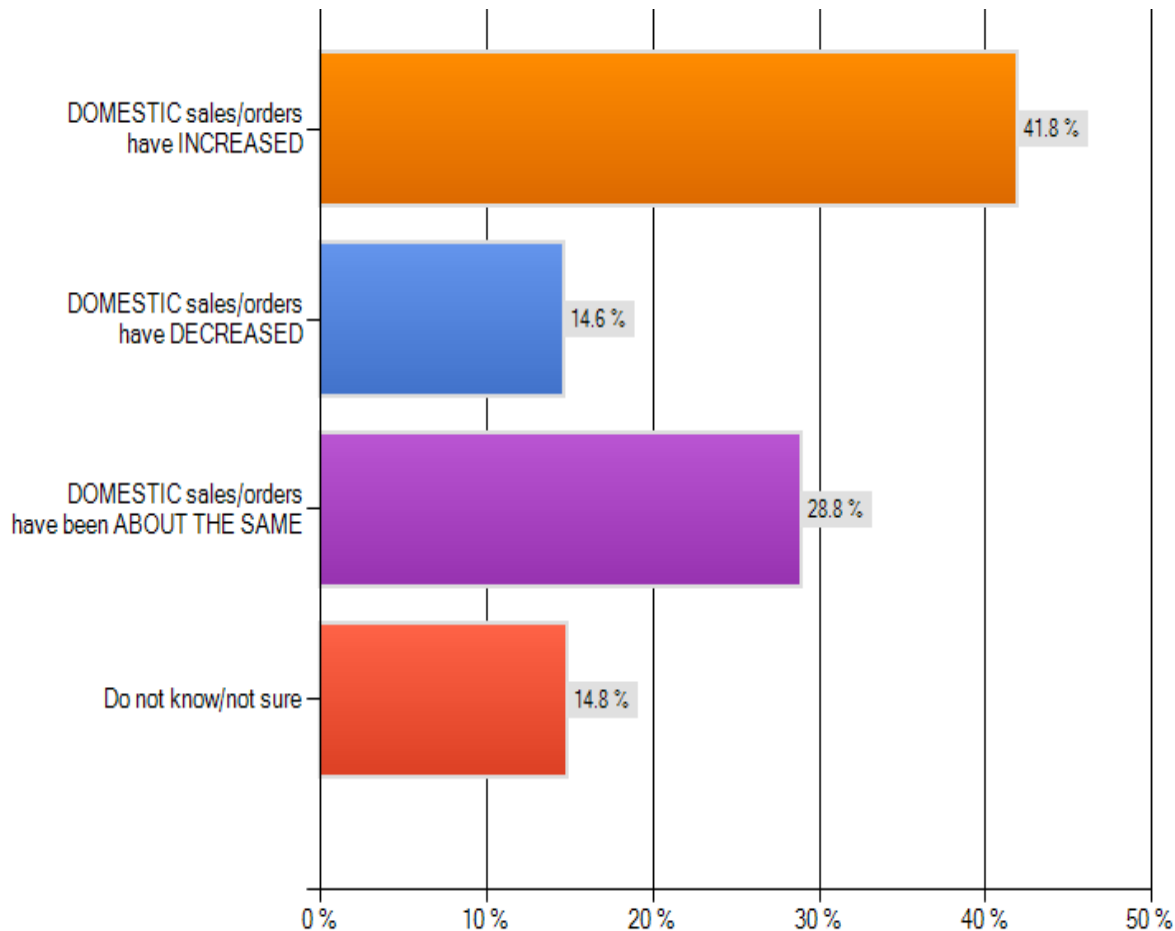
Roughly 42% of survey respondents reported domestic sales increases during 2011, and more than half of all respondents reported increased international sales. A vast majority (more than 70%) of survey participants expect their strong performances to continue through 2012; nearly 70% of firms also anticipate very or somewhat positive business conditions this year, and more than half of firms expect to hire additional employees to handle new business.

While many survey participants expressed concern regarding regulatory uncertainty and a new tax on revenue in the United States, other expressed optimism about the potential in emerging markets including Brazil and China. One thing was clear – the medical device industry will continue to look for opportunities beyond their borders in 2012.

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Has there been a change in DOMESTIC sales for your company during 2011?



Asia on the rise, Europe stumbles

Overall, companies reported that domestic device sales improved by roughly five percentage points in 2011 compared to 2010.

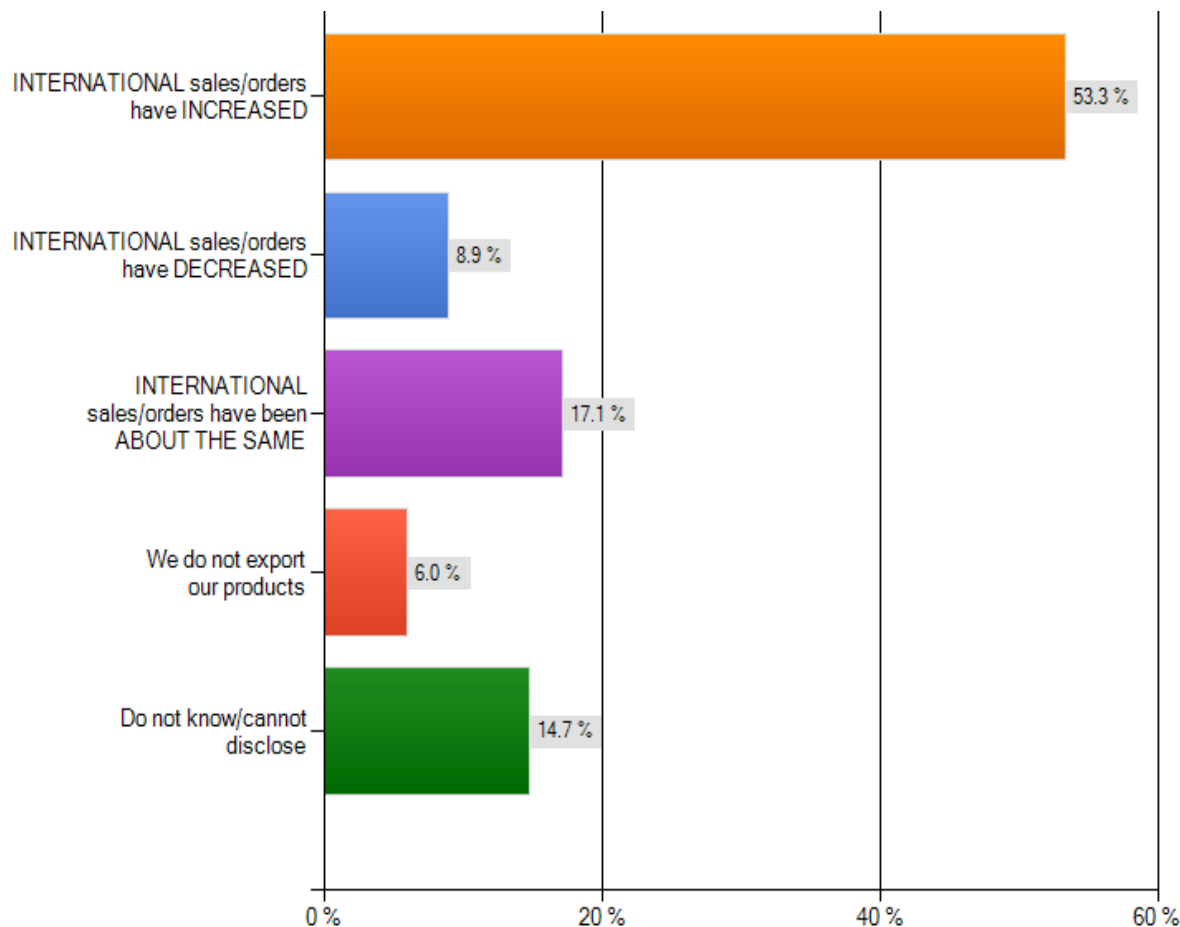
However, the results varied widely depending on where the company was located. Just over 49% of firms in Asia-Pacific markets reported domestic sales increases, while only 35% and 33% of firms in Europe and the Middle East respectively saw increases. The disparity makes clear the impact a struggling European economy is having on firms located on the continent. North American firms fared better, about 42% reported higher domestic sales.

Survey results from late 2010:

- 37.1% saw increased domestic sales in 2010
- 15.5% saw decreased domestic sales in 2010
- 26.6% saw no change in 2010
- 20.9% were not sure

*Based on 1,647 responses worldwide
January 2012*

Have you noticed a change in your INTERNATIONAL sales in 2011?



Firms seeking opportunities abroad

The numbers would seem to indicate that firms focused more on international sales in 2011, perhaps as a means of supplementing anemic domestic sales. As in 2010, international sales growth outpaced domestic sales among survey participants.

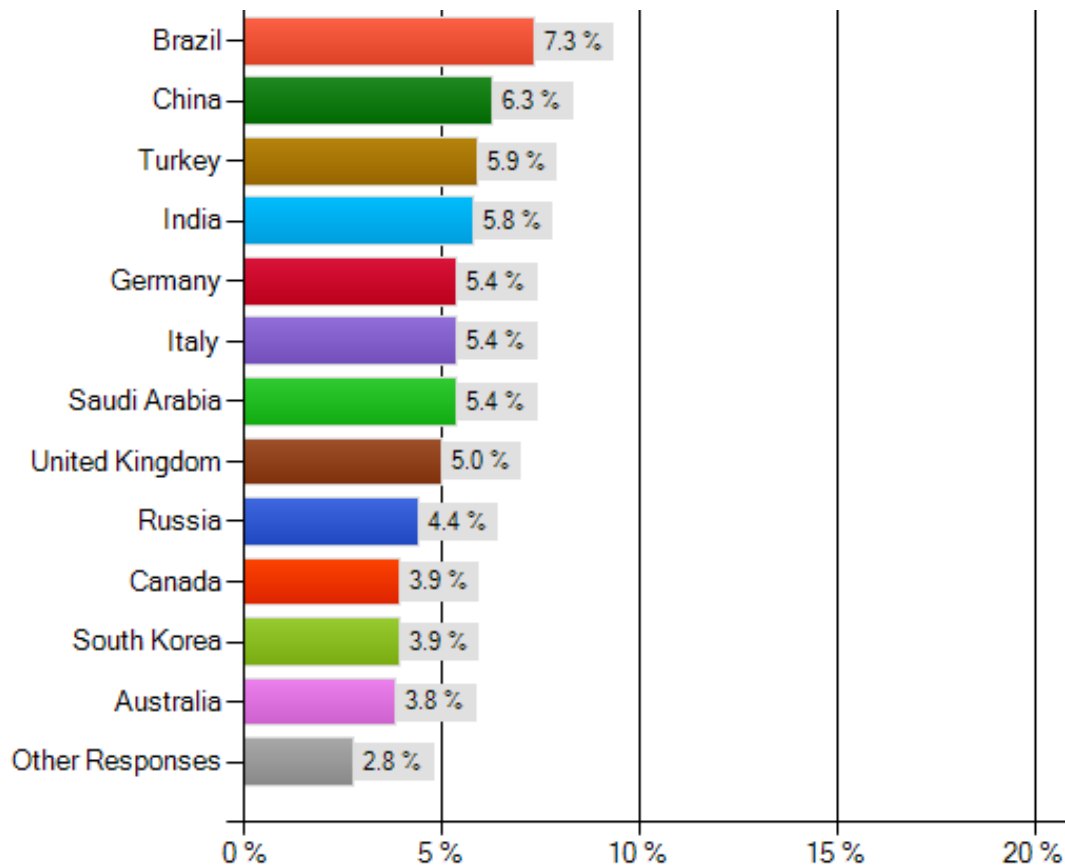
Nearly 55% of North American firms reported international sales growth, as did 51% of all European firms. Interestingly, while half of all Asian manufacturers reported increased international sales, the largest gains by these firms seem to be coming from their own domestic markets.

Survey results from late 2010

50.5% saw increased international sales
10.1% saw decreased international sales
16.4% saw no change from 2010

*Based on 1,657 responses worldwide
January 2012*

Did your company enter new INTERNATIONAL markets in 2011?



International expansion continues

Unsurprisingly, popular emerging markets such as Brazil, China and India attracted interest from many medical device firms in 2011. China and Brazil was most interesting to larger manufacturers (1000+ employees) with the resources to navigate those more complex markets.

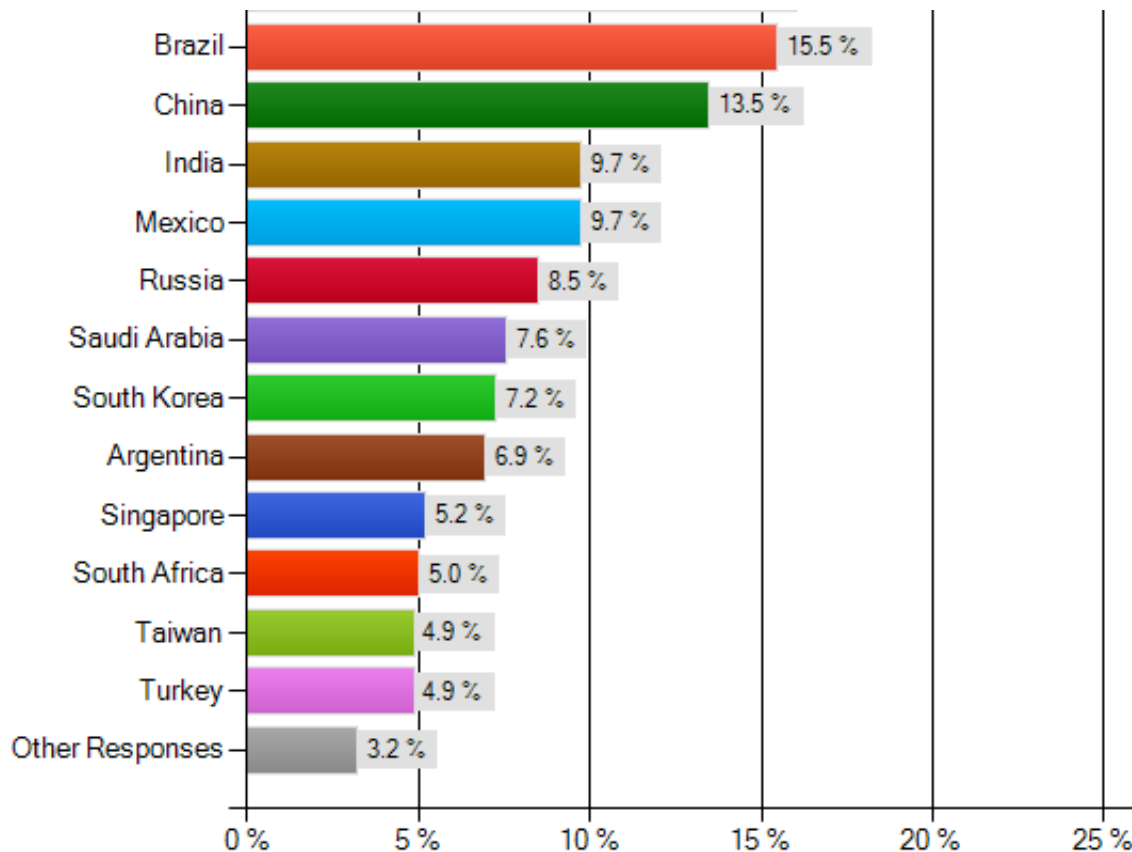
In late 2010 we asked which countries firms PLANNED to enter in 2011. At that time, 23% said China, 21% said Brazil, and 15% said India. As the data shows, it seems that far fewer companies realized their goal.

As expected, smaller firms (under 50 employees) sought established markets including Germany, the UK and France—a trend carrying over from previous years.

Notable in this year's survey was the fact that firms are starting to focus on other markets such as Saudi Arabia and Turkey.

*Based on 1,225 replies worldwide.
January 2012*

Do you plan to enter any of the following emerging markets in 2012?



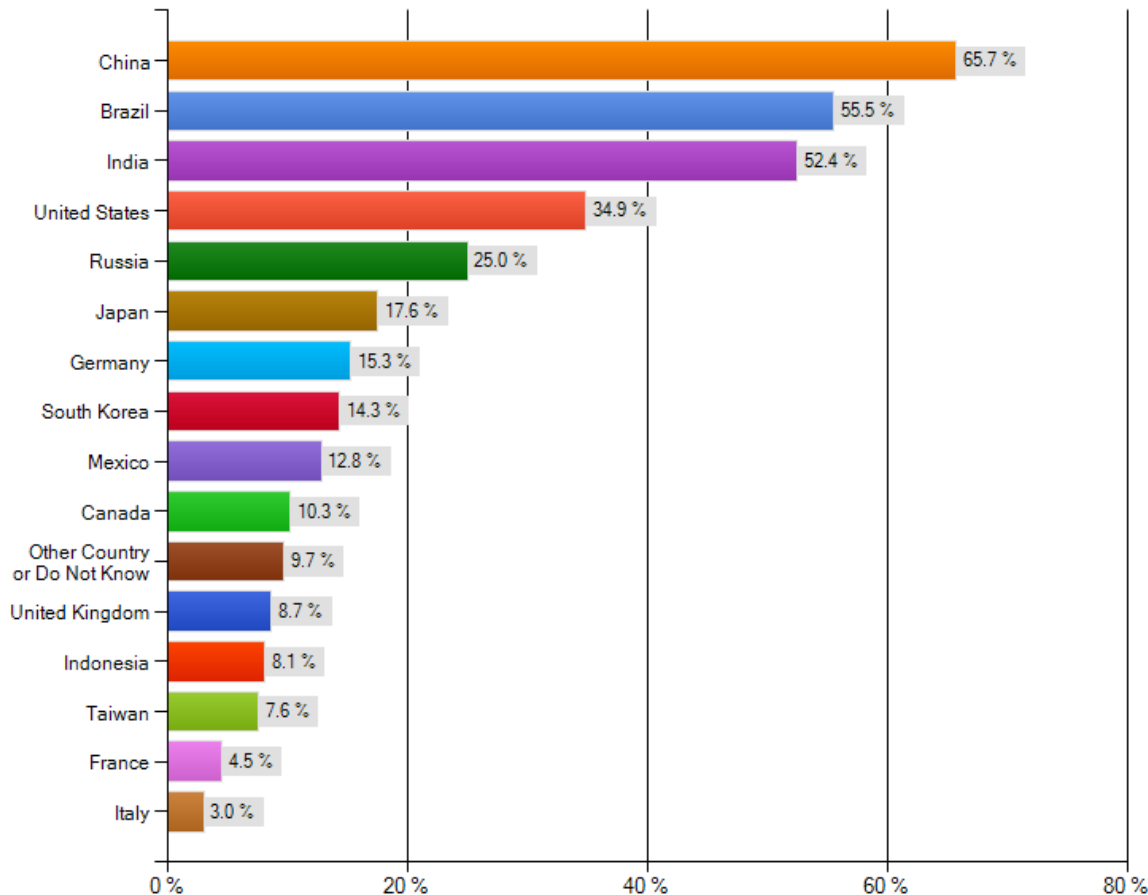
As in last year's survey, participants continue to be enamored with emerging markets including Brazil, China and India.

Mexico also scored highly among small-tier firms, due perhaps to the country's policy introduced in late 2010 allowing expedited reviews for many devices already commercialized in the US or Canada.

About half of all North American respondents indicated plans to enter China this year, whereas most European and Asian firms chose Brazil.

*Based on 1,215 replies.
January 2012*

Which markets offer the best growth potential over the next five years?



Growth potential

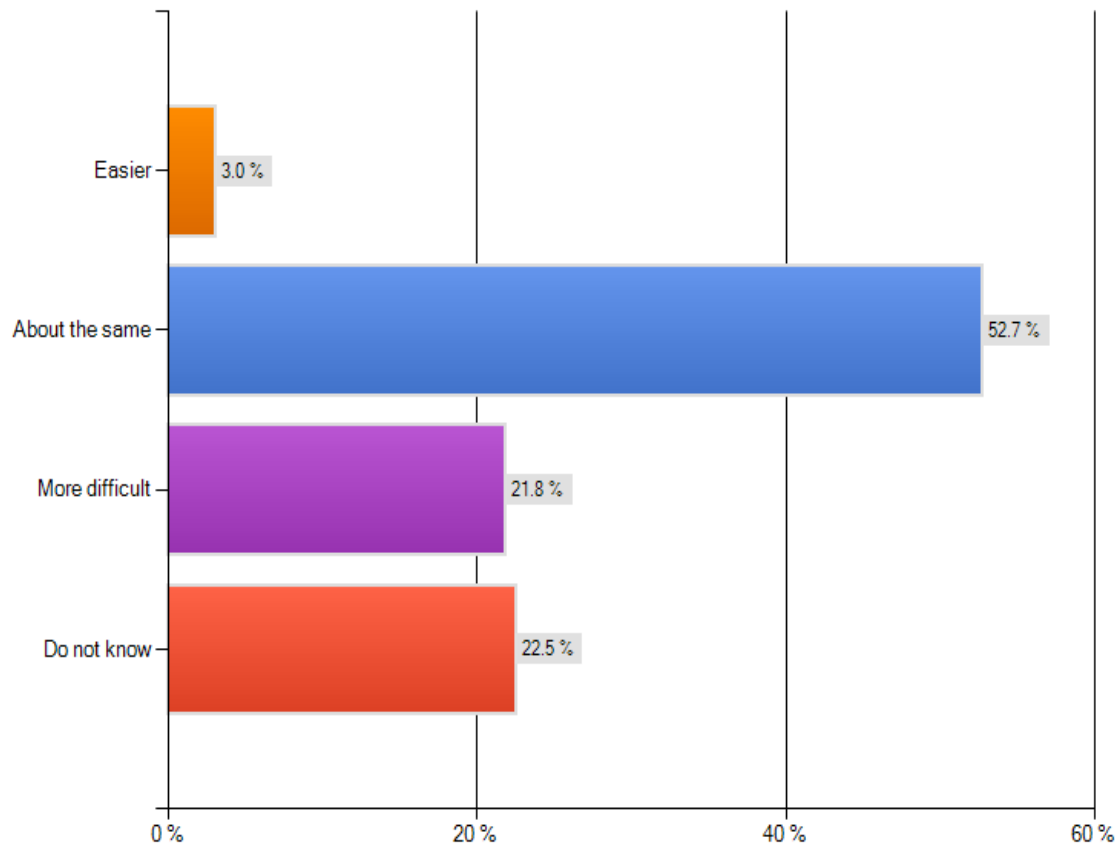
China, Brazil and India continue to lead the pack in terms of markets with the best perceived growth potential. Even the US market, seen as becoming more challenging for manufacturers, received fairly high marks from 35% of respondents. Due to its sheer size, even modest growth in the US market would dwarf that in other faster growing markets such as Brazil and China if measured by revenue.

China's rating decreased from 79% to 66%, perhaps due to new clinical requirements and stricter regulatory oversight by the China SFDA. India also dropped from 70% to 52%. On the flip side, Brazil increased from 46% to 56%.

Half of all small survey participants with less than 50 employees viewed the US as a high-growth market on par with the BRIC countries over the next five years, whereas the largest respondents (firms with 1000+ employees) overwhelmingly chose China, Brazil and India as markets with the best near-term growth potential.

*Based on 1,939 replies.
January 2012*

Is the European CE Marking process easier or more difficult that it was one year ago?



CE Marking process gets tougher

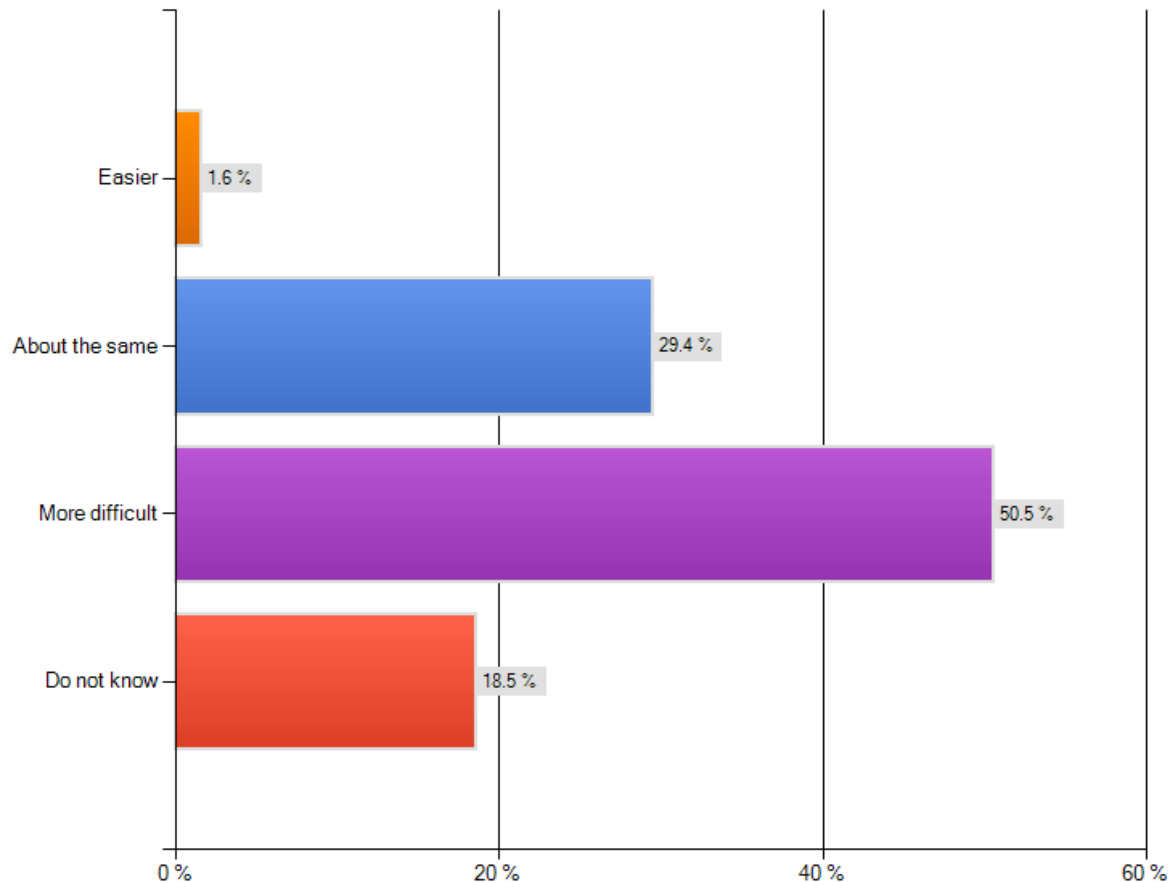
Compared to the US, the European Union has been touted by some medical device industry advocates as a more predictable and efficient regulatory process.

Survey results do not indicate that argument necessarily holds true. While most respondents saw no change in the CE Marking process, nearly 22% of firms indicated that the process had become more challenging in 2011. The most likely explanation is that the provisions of Directive 2007/47/EC took hold in 2010 and were enforced more stringently by Notified Bodies in 2011. One such provision increased the requirements for clinical data by manufacturers.

More smaller manufacturers (22%) than largest-tier firms (17%) indicated that the CE Marking process had become more difficult last year; most likely because larger firms have more in-house regulatory resources to handle increasing regulatory oversight.

*Based on 1,906 replies worldwide.
January 2012*

Is the US FDA clearance/approval process easier or more difficult than it was one year ago?



US FDA process becoming more rigorous

Industry advocates argued throughout 2011 that the US FDA's device review process has become more complicated and less predictable.

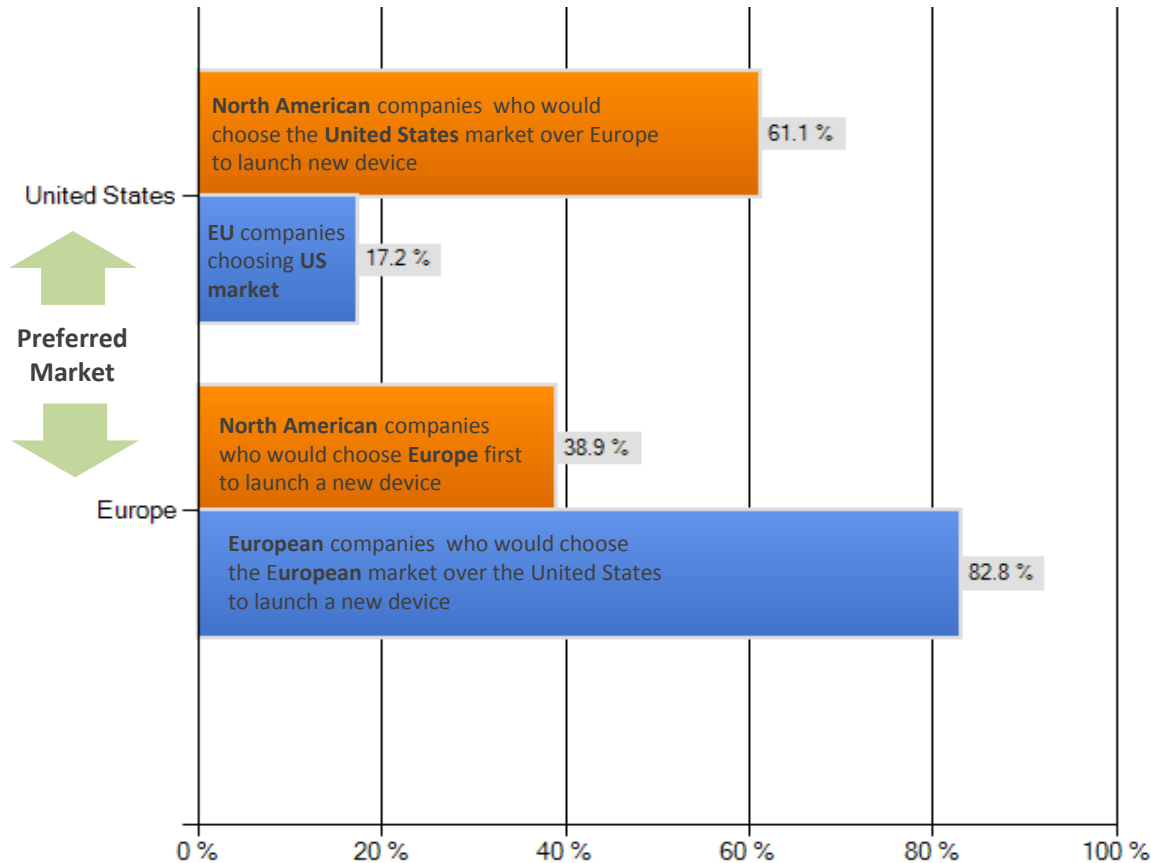
Now, survey participants seem to have verified that argument, with more than half of all firms reporting that the US FDA regulatory process has become more difficult in 2011.

This perception was stronger among larger firms, 59% of which said FDA reviews were more challenging; 44% of smaller firms also reported greater difficulties.

Industry trade groups have argued that a more challenging FDA clearance process will drive away US market participants in favor of other markets, but as the next slide illustrates, companies find it difficult to ignore the sheer size of the US market despite the challenges.

*Based on 1,909 replies.
January 2012*

Other factors being equal, would you choose to launch a new product in the US or Europe first?



US or Europe first?

As the US regulatory environment for becomes more challenging, industry observers have warned that Europe might emerge as the preferred market for manufacturers when choosing where to launch new products.

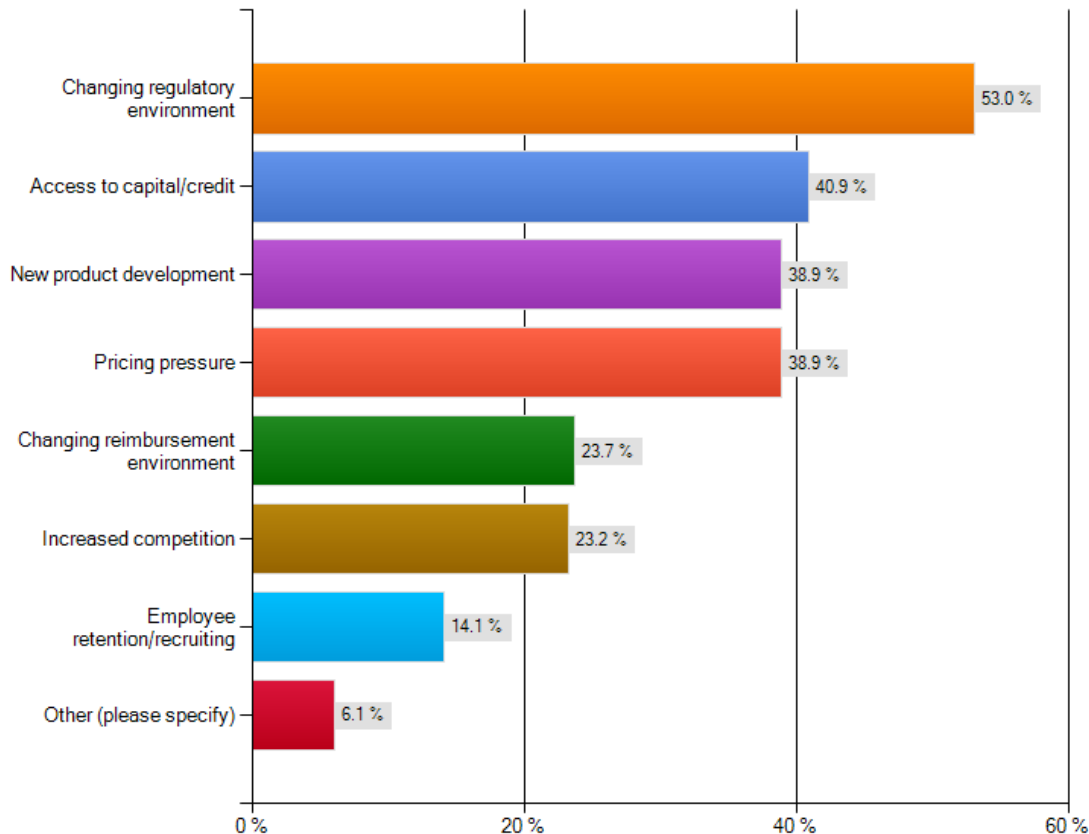
To address this issue, we asked respondents which market they would prefer if sales/turnover potential, and cost/time to obtain regulatory approval were the same in both markets.

The warnings of industry observers seem to be well founded. Fully 39% of North American companies said they would choose the Europe market first to launch a new device, and nearly 83% of companies located in Europe said the same thing.

These results seem to support the perception that the US regulatory process has become more difficult, and companies are acting by choosing to launching in what is perceived as a more predictable regulatory environment.

*Based on 1,866 replies.
January 2012*

What are the biggest challenges you face in running your business?



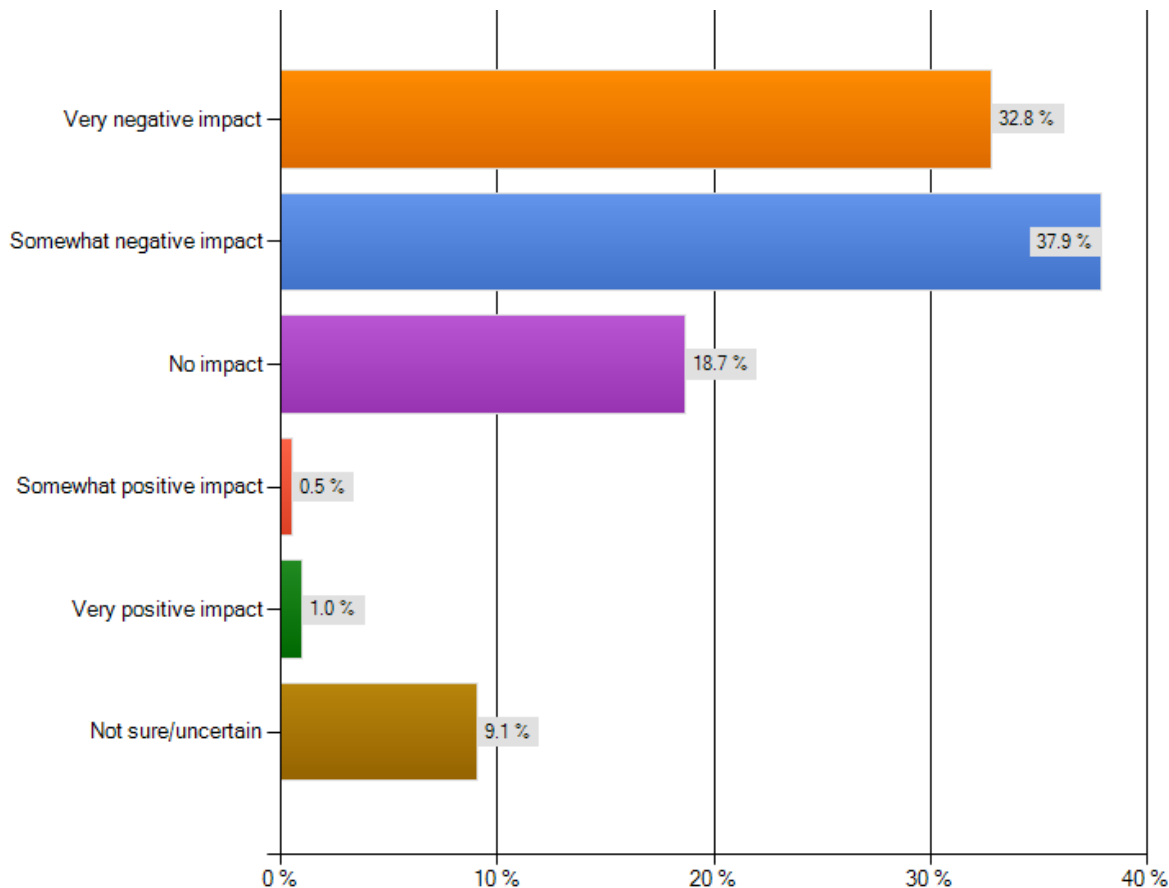
Regulatory challenges on forefront

Addressed only to CEO, President or Managing Director participants, this question revealed changing regulatory environments as most respondents' top concern for 2012. This held true for North American CEOs (59%) as well as Asian CEOs (50%). Although 50% of European CEOs ranked changing regulations as a challenge, more of them (57%) cited new product development as their top challenge. This could reflect perceptions of a more stable and transparent regulatory structure for medical device commercialization in Europe.

Access to capital and pricing pressures also rated highly among all participants—no surprise given global economic conditions.

*Based on 198 replies from CEO, President and Managing Director titles only.
January 2012*

What impact will a scheduled 2.3% excise tax on device sales in the US have on your business?



Impact of US medical device tax

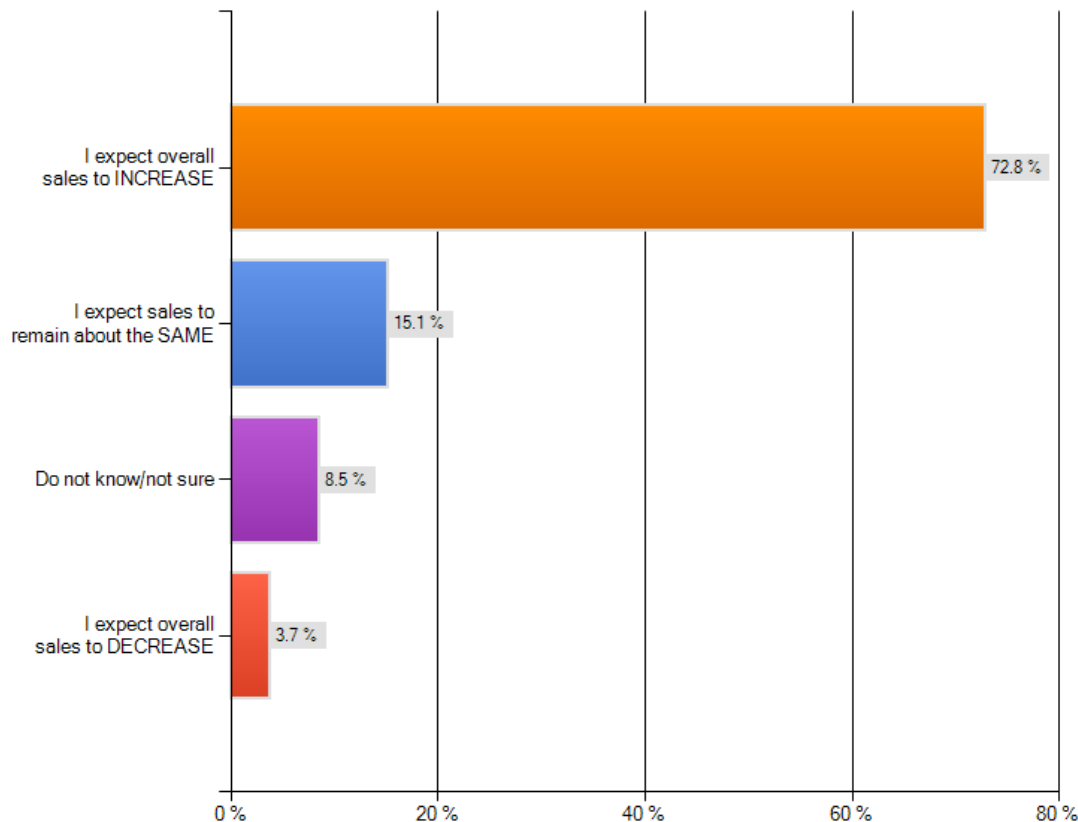
With the US government scheduled to implement a 2.3% excise tax on medical device sales in 2013, we asked CEOs, Presidents and Managing Directors how they expect the tax to affect their business. Not surprisingly, few respondents took a positive view of the issue.

More large-tier firms took “very” (43%) or “somewhat negative” (57%) views of the tax’s impact than did smaller manufacturers; 36% of small firms took a very negative view, and 38% took a somewhat negative view.

Of course, for large firms with huge sales volumes, the impact on the bottom line will be much more noticeable, albeit no less painful.

*Based on 198 replies.
January 2012*

How do you feel about prospects for your company in 2012?



General optimism for 2012

Expectations of increased sales were high among survey respondents of all sizes and locations—although down slightly from last year's survey.

More than 80% of small firms anticipate increased sales in 2012, as do 72% of large firms.

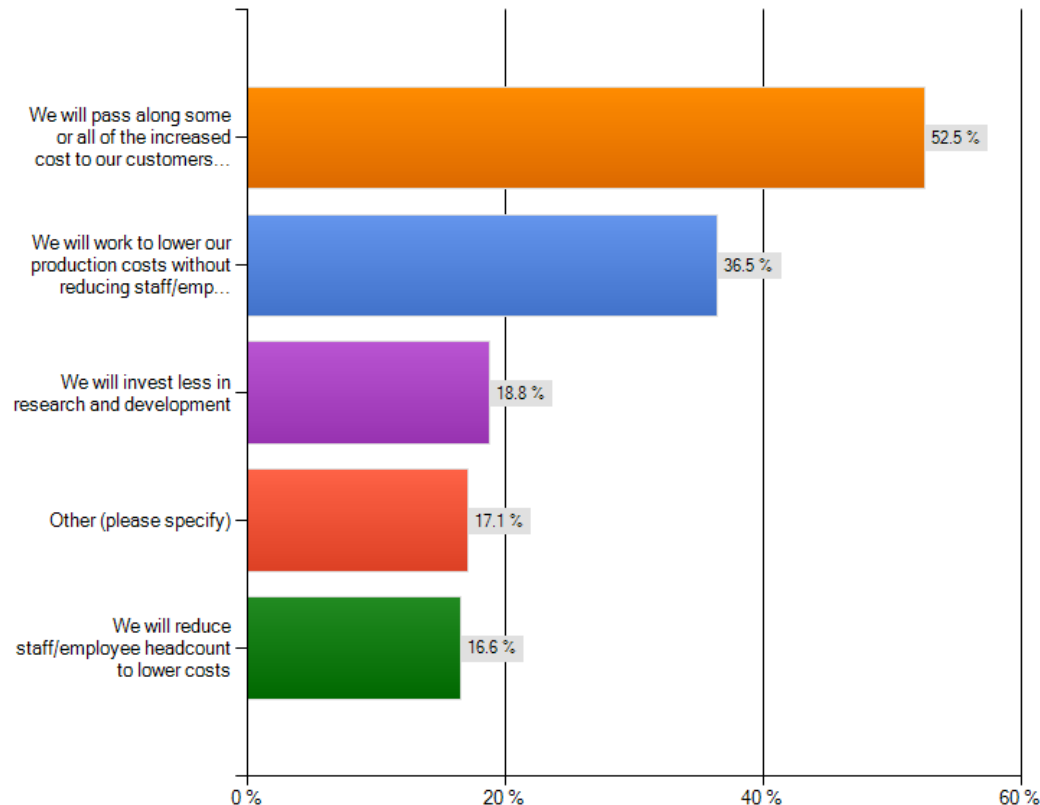
North American manufacturers (77%) were slightly more optimistic than their European and Asian counterparts (73% each), but firms in all major markets clearly expect sustained growth trajectories this year.

Survey results from late 2010

74.6% expected overall sales increases
2.8% expected overall sales to decrease
14.4% expected sales to remain the same
8.3% did not know

*Based on 2,354 replies
January 2012*

Will you make any of the following changes in 2012 before the US excise tax takes effect?



Preference to reduce costs, not employees

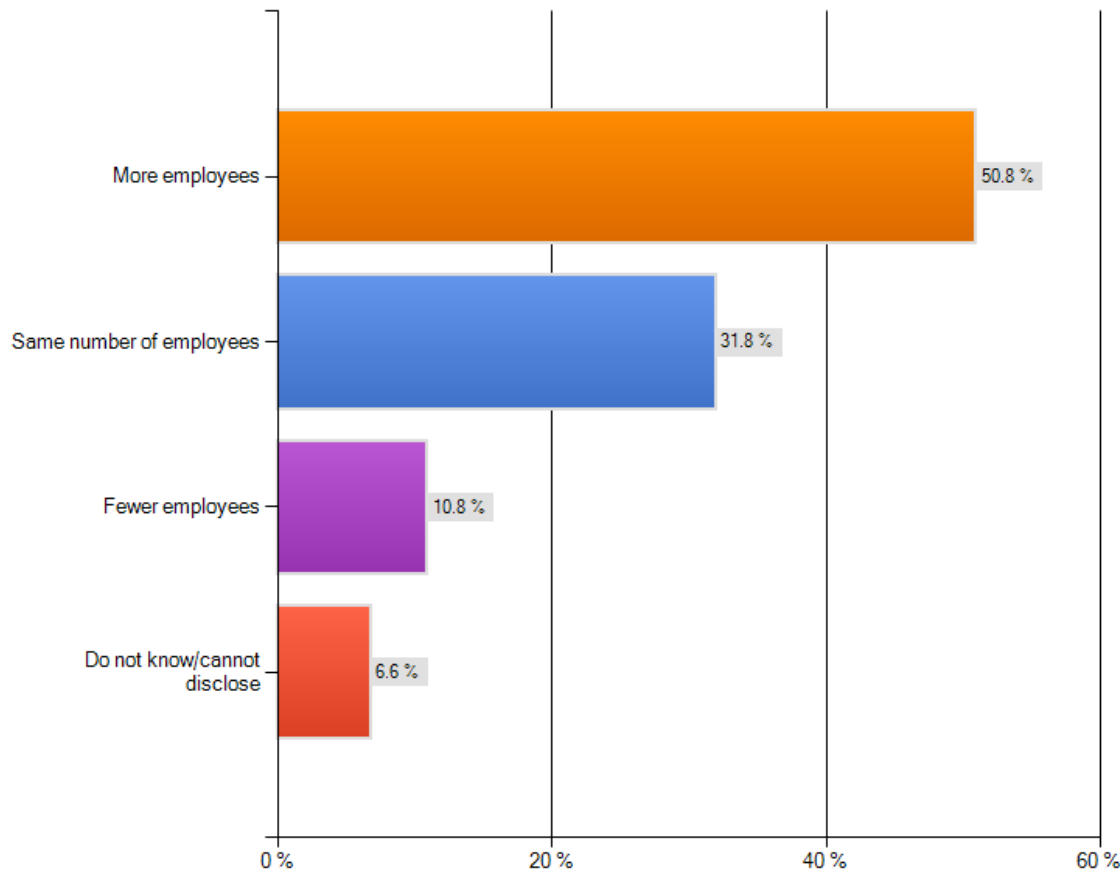
Over the past year, some industry organizations have warned that manufacturers will be forced to cut headcount in order to offset effects of the US excise tax once it becomes law.

We asked this question of CEOs, Presidents and Managing Directors only and our survey results show a much different story. Across the board there is bigger inclination among firms to raise prices and pass on costs to customers as a way to deal with the US tax, or to lower production costs. Larger manufacturers, in particular said they would work to lower production costs.

Among North American manufacturers (providing the bulk of responses to this question), staff reductions ranked well behind raising product prices (58% of firms), lowering production costs (34%) and reducing R & D investments (26%). Clearly, despite dire predictions to the contrary, companies clearly plan to deal with the new tax NOT by cutting employees, but cutting costs in other ways.

*Based on 181 replies.
January 2012*

Will your firm have more or fewer employees in 2012?



Industry hiring will continue

Medical device firms' hiring plans appear to remain healthy, but rates are down slightly from last year's survey.

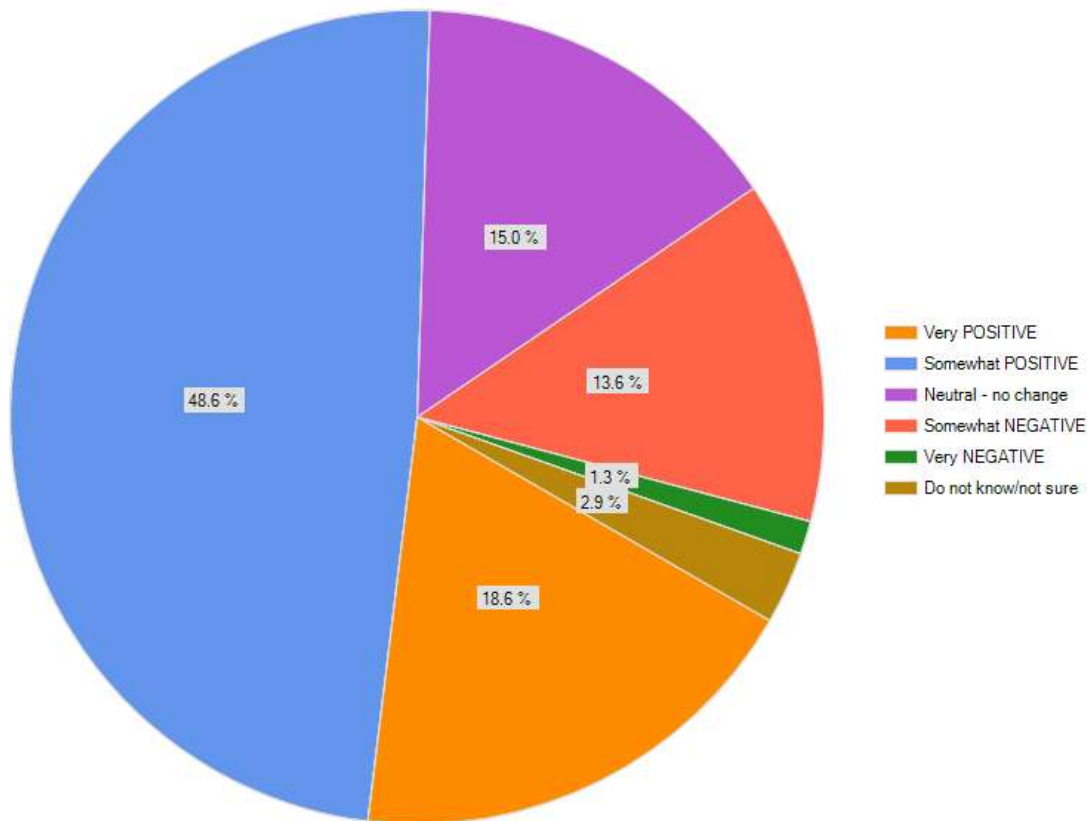
Fewer respondents (51%) this year expect hiring to increase compared to 56% of last year's survey respondents. Nearly 11% of respondents expect fewer employees in 2012, up from 7% in 2011.

Despite tough times in Europe, medical device firms in Europe (49%) seem just as likely to hire more people in 2012 as their North American (52%) counterparts. About 13% of North American and European firms expect to reduce staff, compared to 8% of Asian firms.

Unlike last year, CEOs were only slightly more optimistic (56%) than QA/RA staff (52%) that 2012 hiring would increase. (Nearly 66% of CEOs expected increased hiring in our previous survey.)

*Based on 2,351 replies.
January 2012*

What is your outlook on the overall business environment for the medical device industry 2012?



Industry remains positive for 2012

Most of this year's survey participants took a "very" or "somewhat positive" view of the overall business environment going into 2012.

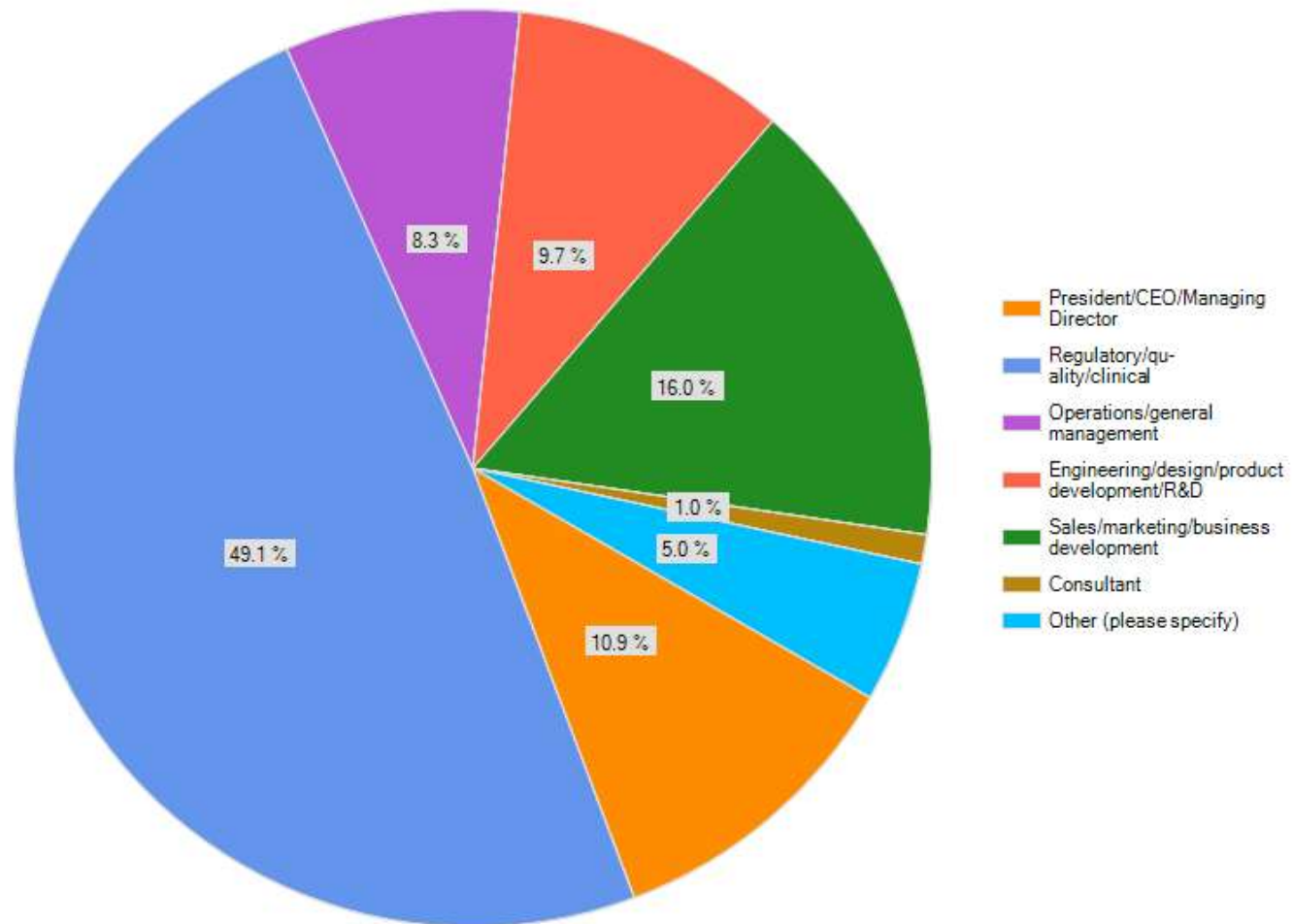
"Somewhat negative" views, however, saw a slight uptick, from 10.3% of respondents last year to 13.6% of firms in this year's survey. These responses were stronger among larger-tier firms in North America and Europe. Regulatory challenges in the US as well as worsening economic conditions in Europe no doubt influenced these results.

Accordingly, Asian firms' responses were the most optimistic: 30% of respondents took a "very positive" view of the business environment, and 49% took a "somewhat positive" view.

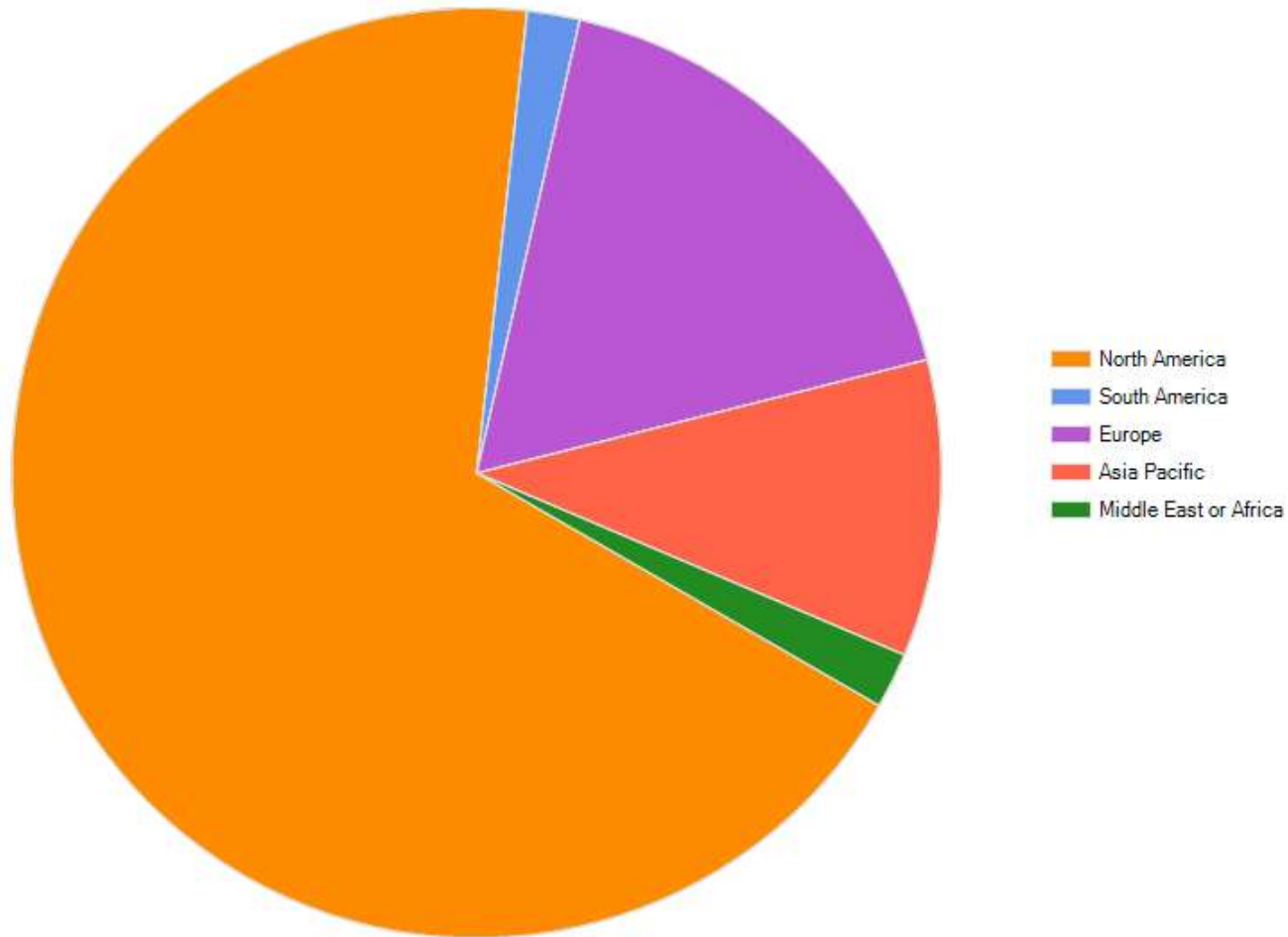
Despite ongoing economic and regulatory challenges, the industry remains positive about its prospects for the coming year.

*Based on 2,354 replies.
January 2012*

Survey participants by job function



Survey participants by location



Methodology and Mission

The 2012 Medical Device Industry Survey was conducted between December 1, 2011 and January 5, 2012, with a total of 2,613 participants. Only one response per person was allowed. Survey questions were emailed to in-house lists maintained by Emergo Group, Medical Device Summit and Mass Device. A publicly available online link to the survey also solicited responses from industry professionals.

Due to the nature of the lists maintained by Emergo Group and its partners, regulatory and quality assurance professionals and participants based in North America made up a majority of the survey's participants. Results should be interpreted bearing these factors in mind.

Questions regarding sales targeted only medical device and IVD manufacturers; questions regarding business challenges, the pending US medical device excise tax and its effect on 2012 business plans were addressed only to CEOs, Presidents and Managing Directors.

Emergo Group fully understands that this research was not conducted in a scientific manner and some results are not necessarily statistically valid due to small sample size in some subgroups of data. Still, our intention in conducting the 2012 Medical Device Industry Survey is to provide a high-level snapshot of the industry's current condition and its prospects over the coming year. We hope you find this information valuable.

If you have any questions regarding these results, please contact:

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