EMERGO

Global Medical Device Industry Outlook for 2017

Based on a survey of more than 3,000 industry professionals

January 2017

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Executive Summary - January 2017

Dear Reader:

As we enter 2017, one thing we know for certain is that we can never really be certain about anything… except that the pace of change seems to accelerate with each passing year.

In the US market, companies are trying to figure out what will replace the soon-to-be-dismantled Affordable Care Act and what this means for their long term sales prospects in the world's largest healthcare market.

In Europe, the introduction of strenuous new medical device regulations and ongoing currency exchange differential has some smaller American device companies pulling out of the market.

In Brazil, a stagnating economy continues to take some shine off what used to be the brightest market in the western hemisphere.

And in China, regulations seem to appear out of nowhere with immediate effect, leaving many scratching their heads about how to appease the CFDA.

Yet, despite all the uncertainty, the 3,000+ people who took our 9th annual medical device industry survey are surprisingly optimistic about 2017.

Key takeaways from our 2017 survey:

- One third of companies saw more than 10% increase in 2016 sales/turnover (page 4)
- BRIC has lost its luster. Companies seem more optimistic about 2017 sales/turnover gains from the traditional markets of US and Europe rather than the developing markets (page 5)
- …but companies are still confident long-term growth will come from Asia, mostly China (page 6)
- Pricing and profitability pressures continue to plague larger companies (page 8)
- Overall, regulatory compliance has become much more difficult, especially in Europe (page 12)

While the industry faces several headwinds, we are happy to report that it is not stopping the medical device industry from marching full steam ahead. In nearly every developed and developing market, the population continues to get older (Europe) and/or richer (China) and these two macroeconomic factors will continue to drive demand for more healthcare, and a need for more devices.

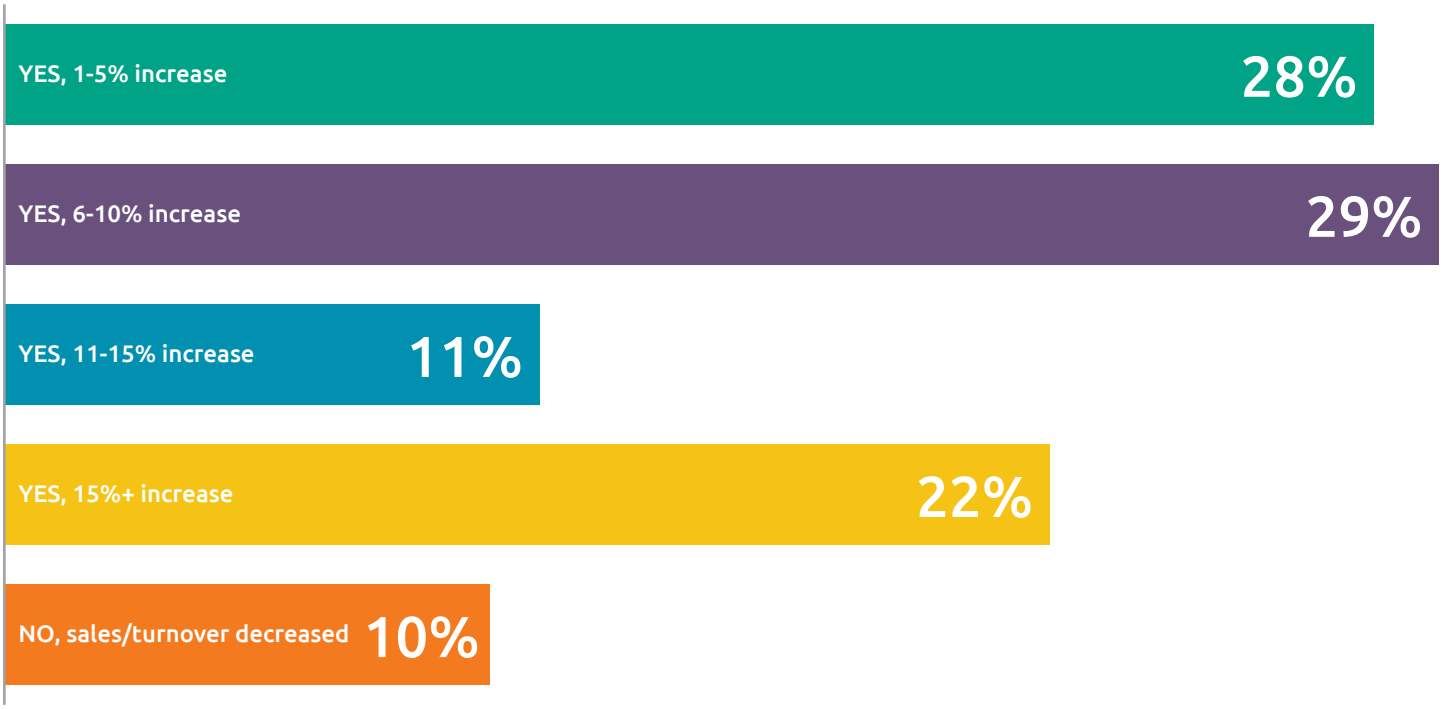
So while uncertainty prevails, we expect 2017 will be another solid year for the industry despite government desires to slow per capita healthcare spending in many markets worldwide.

Regards,

Chris Schorre
VP of Global Marketing | marketing@emergogroup.com

Did (or do you expect) your company to experience an increase in worldwide sales/ turnover in 2016?

2016 seems to have been a pretty decent year for medical device companies. About 1/3 of all companies reported sales/turnover increase in excess of 10%. Only 10% of companies saw their sales/turnover drop.



Sales/turnover results for 2016 segmented by company size

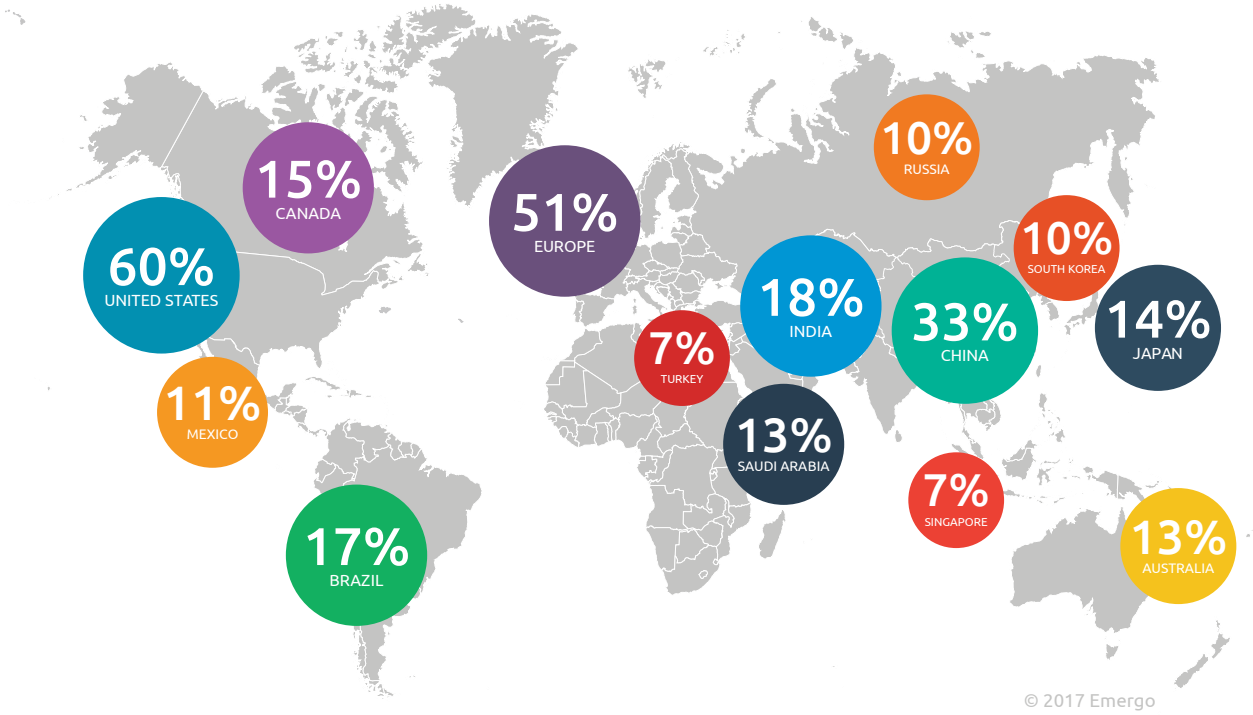
Number of Employees	YES, 1-5% increase	YES, 6-10% increase	YES, 11-15% increase	YES, 15%+ increase	NO, sales/ turnover decreased
1-9	25%	15%	11%	34%	15%
10-49	24%	24%	9%	31%	12%
50-249	27%	31%	13%	18%	11%
250-999	32%	33%	10%	19%	6%
1000+	34%	40%	11%	10%	5%

Perhaps not surprisingly, companies with fewer than 50 employees were far more likely to see sales/turnover increases of 15% more than larger companies.

Based on 1,452 responses.

Which markets do you expect to produce the strongest growth in sales/turnover for your company in 2017?

This year's survey shows faith in the US and Europe to provide the strongest growth for medical device companies. In our 2016 survey, 51% said the US would provide the strongest growth with 40% indicating Europe. Those numbers expanded to 60% and 51% respectively in the 2017 survey. But that optimism did not spill over to emerging markets. In 2016, 44% thought China would produce strong growth with India at 27% and Brazil at 24%. These particular BRIC markets saw notable declines in optimism compared to a year ago.



Noteworthy changes between 2016 and 2017		
Country	JAN 2016	JAN 2017
Brazil	24%	17%
China	44%	33%
Europe	40%	51%
India	27%	18%
Mexico	15%	11%
Saudi Arabia	18%	13%
USA	51%	60%

Based on 2,384 responses.

What do you think about the growth potential for medical device sales/turnover in these regions during the NEXT 5 YEARS?

Medical device companies continue to be very optimistic about long-term prospects of Asian markets, but do not hold high hopes for sales/turnover growth in European markets.

AFRICA

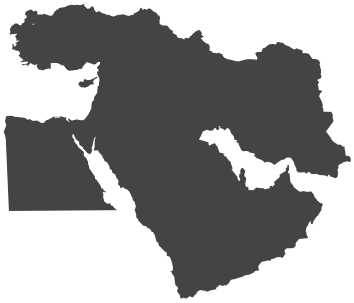
27% 32% 41%

ASIA

63% 32% 5%

EUROPE

18% 56% 26%



MIDDLE EAST

33% 48% 19%

NORTH AMERICA

29% 55% 16%

SOUTH AMERICA

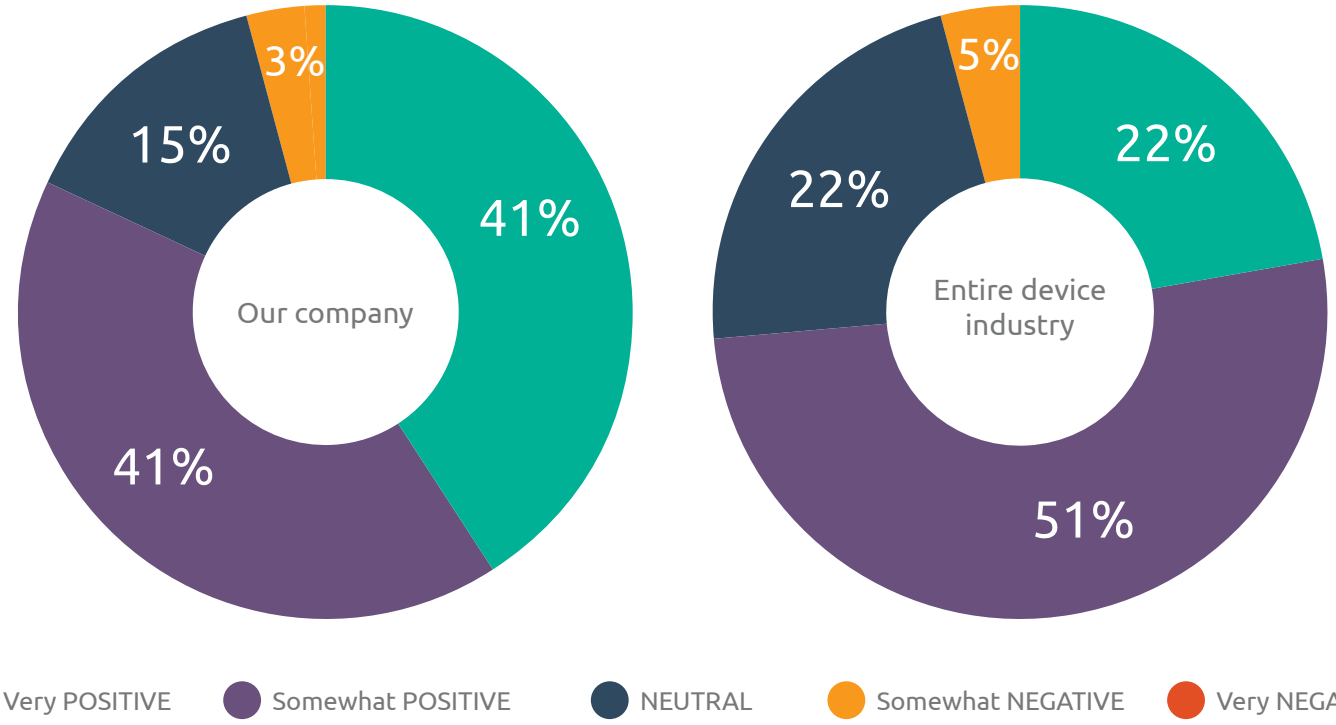
32% 46% 22%

High Growth Potential | Average Growth Potential | Low Growth Potential

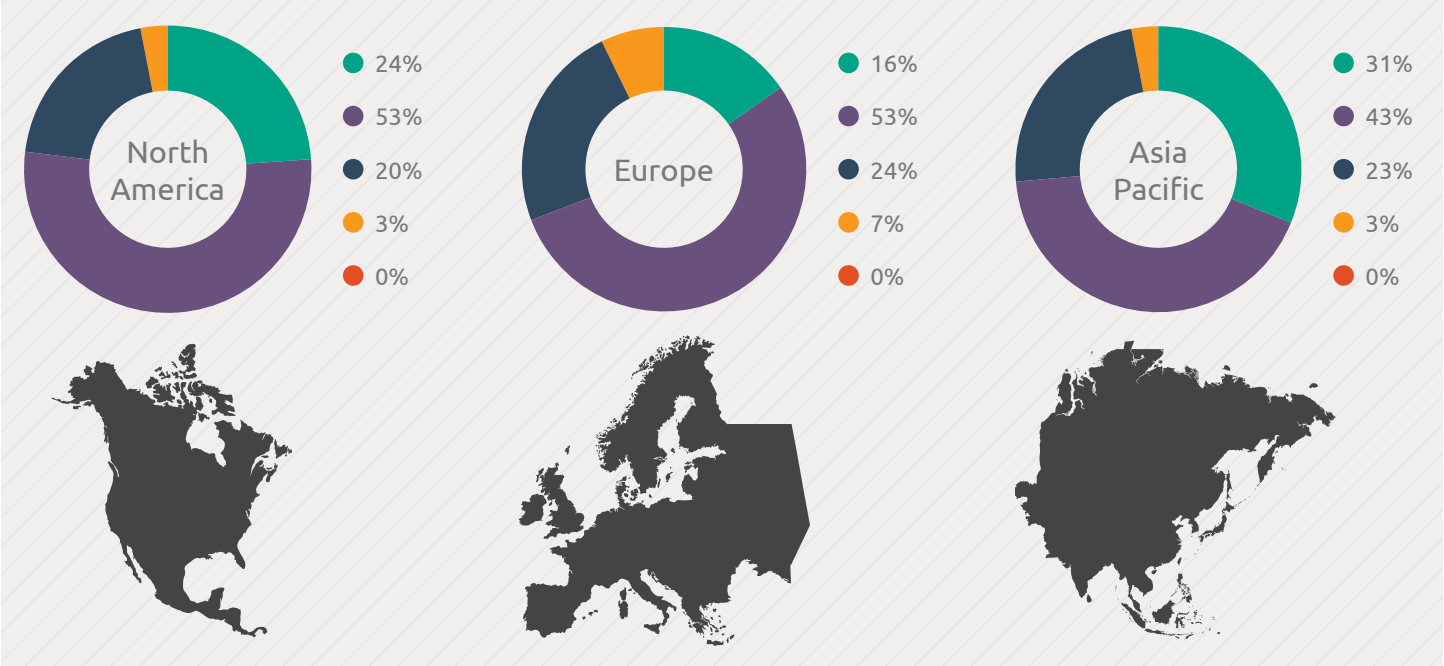
We received between 1,624 responses (Africa) and 2,269 responses (Europe) to this question.

When you think about your company, and the entire medical device industry, how do you feel about 2017?

Our respondents generally have a more positive outlook for their own company than the industry in general. That's not surprising since individuals are always more familiar with the strengths and weaknesses of their own companies than the industry as a whole.



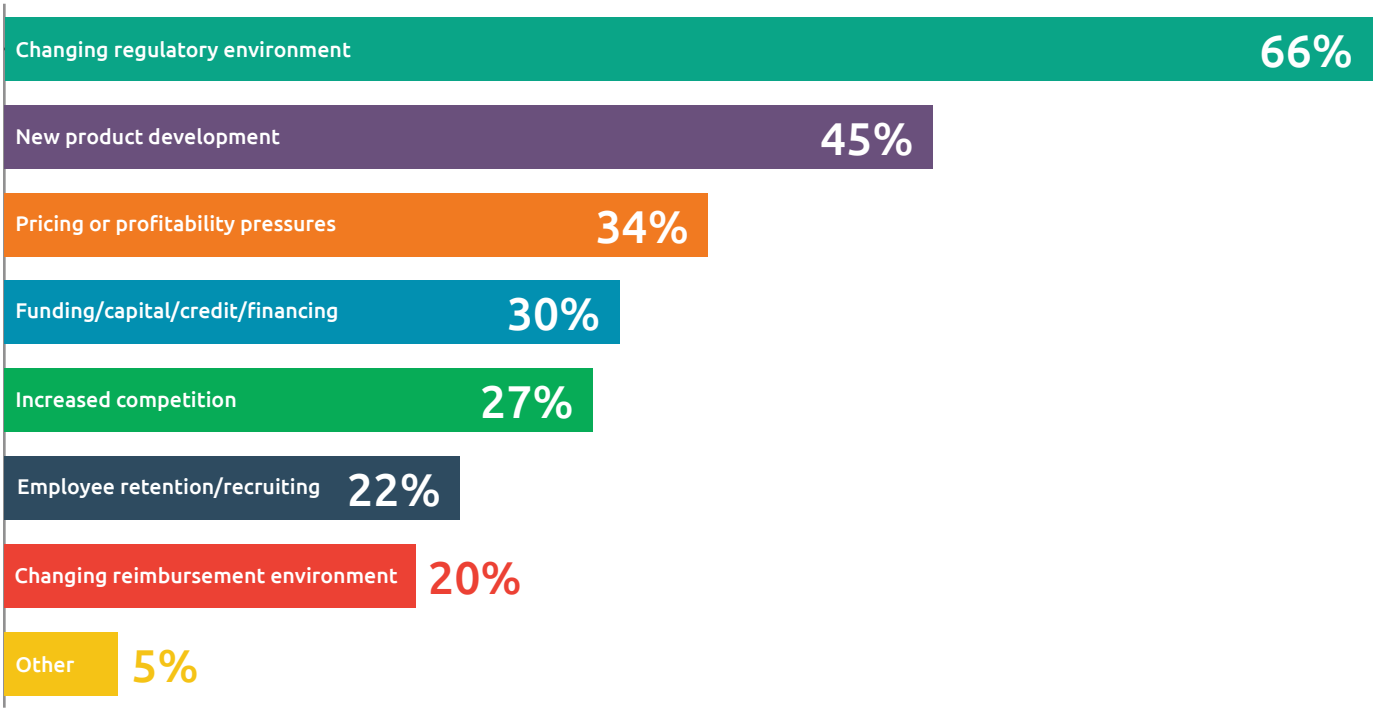
When you think about the entire medical device industry, how do you feel about 2017?



Based on 2,813 responses.

What are the biggest challenges you face?

We directed this question ONLY to people who identified themselves as members of the senior management team (CEO/CXO/President/VP/Managing Director, etc.) within their company. The answers to this question were remarkably similar to last year. Regulatory changes continue to vex companies of all sizes, but are especially challenging for larger companies. As might be expected, funding issues are top of mind among small companies.



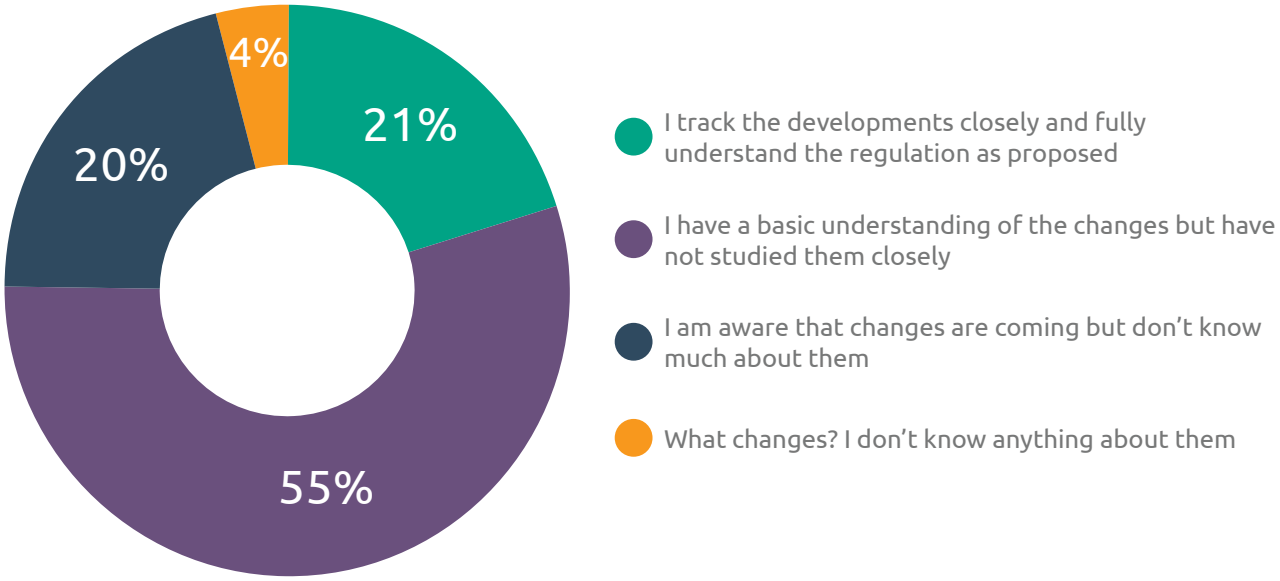
Results segmented by number of employees

Number of Employees	Regulatory changes	Product development	Funding & capital	Pricing pressures	Increased competition	Reimbursement environment	Employee retention
1-9	45%	36%	56%	28%	15%	26%	10%
10-49	61%	42%	39%	30%	20%	15%	21%
50-249	64%	57%	24%	45%	29%	20%	23%
250-999	77%	54%	6%	41%	28%	15%	33%
1000+	74%	49%	13%	46%	51%	32%	36%

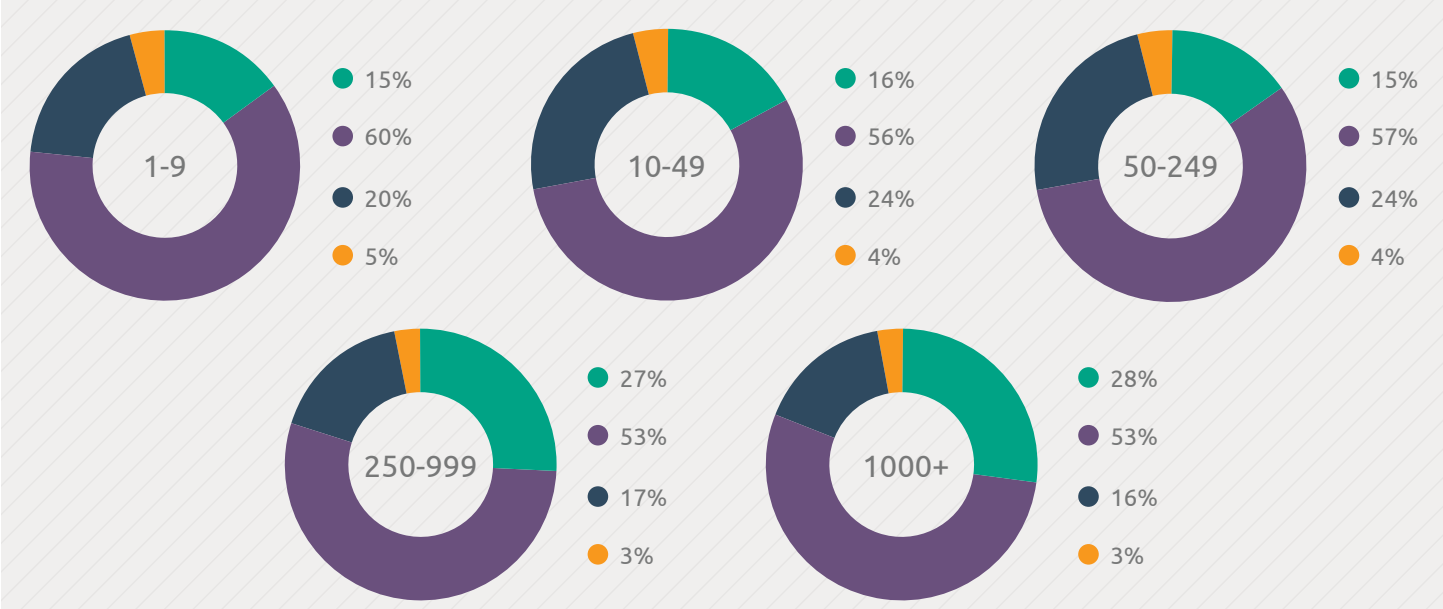
Based on 528 responses from those who identified themselves as a member of the "Senior Management" team. Multiple responses were allowed.

In mid-2016, Europe released a draft Medical Device Regulation (MDR) and In Vitro Device Regulation (IVDR). What is your current level of understanding about these upcoming regulatory changes?

The MDR is the most significant change in medical device regulations in the last 10 years, yet nearly 4 out of every 5 regulatory professionals only have a basic understanding (or less) of the changes in store for their companies. That will certainly change as 2020 draws closer and companies get more serious about compliance. But this raises concern about how Notified Bodies will handle the impending crush of companies scrambling to comply with the new regulations.



Results segmented by number of employees

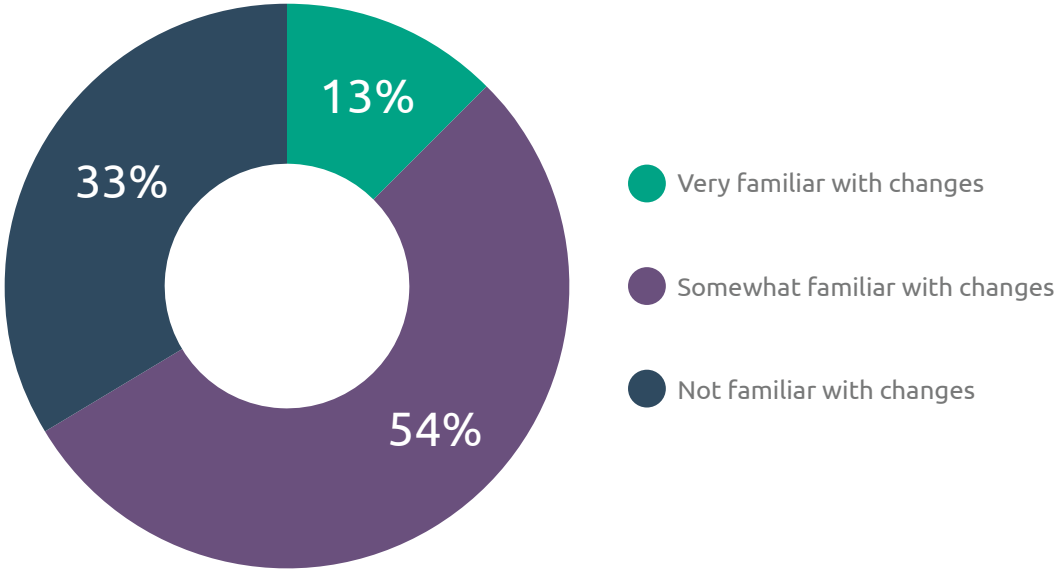


Larger companies have more robust and specialized regulatory departments, so it is not surprising that companies with more than 250 employees are more likely to be well versed on the coming changes to medical device CE Marking regulations. Roughly 25-30% of all QA/RA professionals at smaller device companies with less than 250 employees indicate that they have little or no knowledge of the changes.

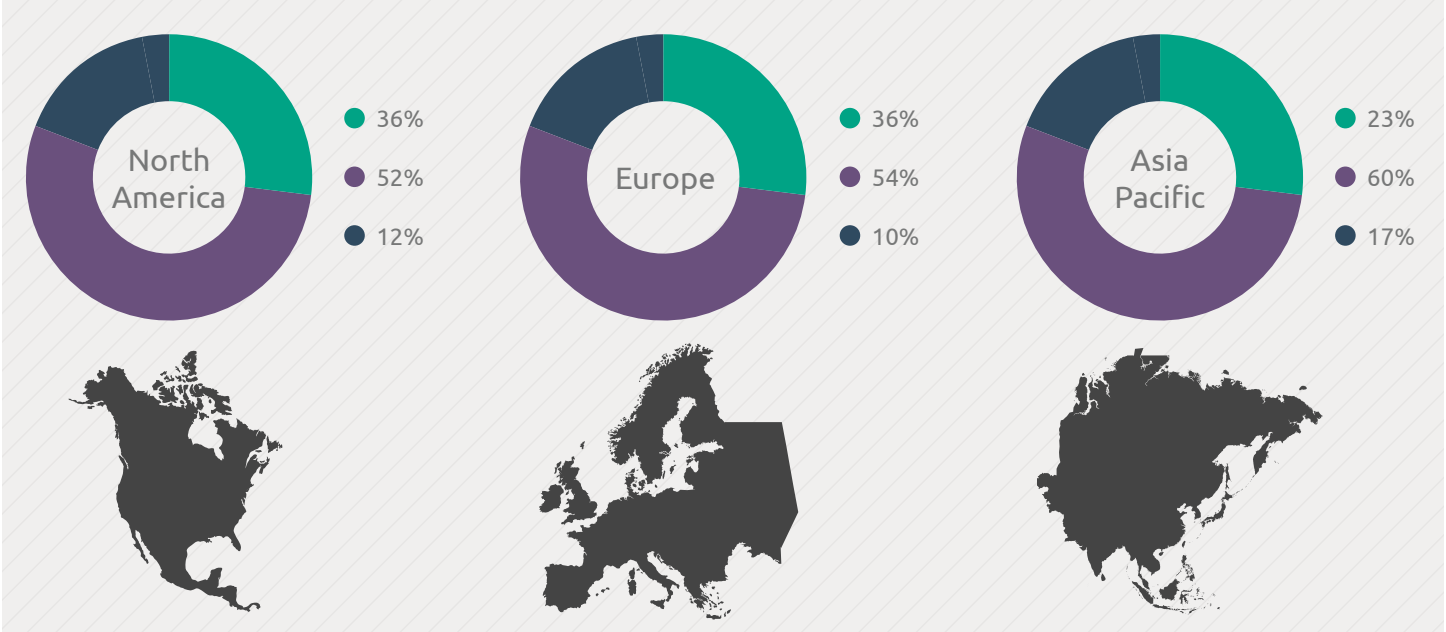
Based on 1,382 responses from QA/RA professionals only.

How familiar are you with the changes required in ISO 13485:2016?

The first major changes to ISO 13485 since 2003 were made in 2016, requiring all manufacturers to upgrade their quality system certification by 2019. Roughly 1/3 of QA/RA professionals are fully aware of the changes that need to be made to their QMS, with another 54% indicating they are "somewhat familiar" with what needs to be done to comply. The ISO 13485:2016 changes, combined with European regulatory changes coming into effect in 2020, mean QA/RA professionals will be in high demand and under intense pressure to maintain certifications for their companies. The pain will be especially acute at smaller companies where the quality and regulatory roles are often combined.



Results segmented by location of respondents



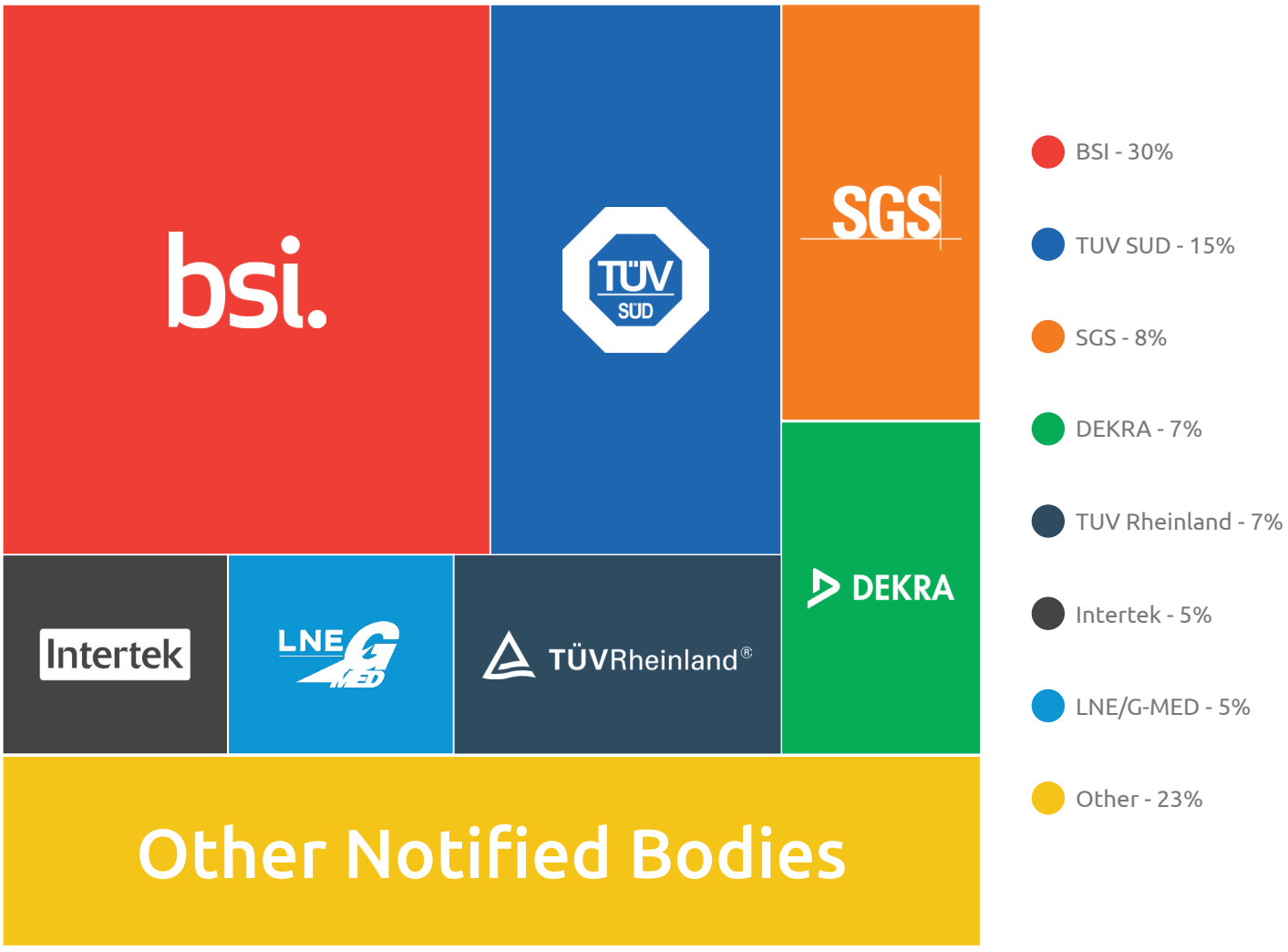
Perhaps not surprisingly, companies located in the Asia Pacific, South American and MENA regions are less likely to be fully aware of the changes forthcoming in ISO 13485:2016, compared to their counterparts in Europe and North America.

Based on 1,380 responses from QA/RA professionals, and only from companies with ISO 13485 certification.

Which company acts as the primary European Notified Body for your company?

Notified Bodies are authorized to audit and certify medical device companies by the Competent Authority (Ministry of Health) in their respective countries. Until recently there were more than 80 entities authorized to audit and certify medical devices for compliance with the European Medical Devices Directive (93/42/EEC). With increased scrutiny and demands placed on Notified Bodies by their Competent Authority overseers, many have dropped out and the number has decreased to 57 as of January 2017. It is expected to drop further as the implementation of the European Medical Device Regulation (MDR) draws nearer. The top seven Notified Bodies shown below audit nearly 3 out of every 4 medical device companies selling in Europe.

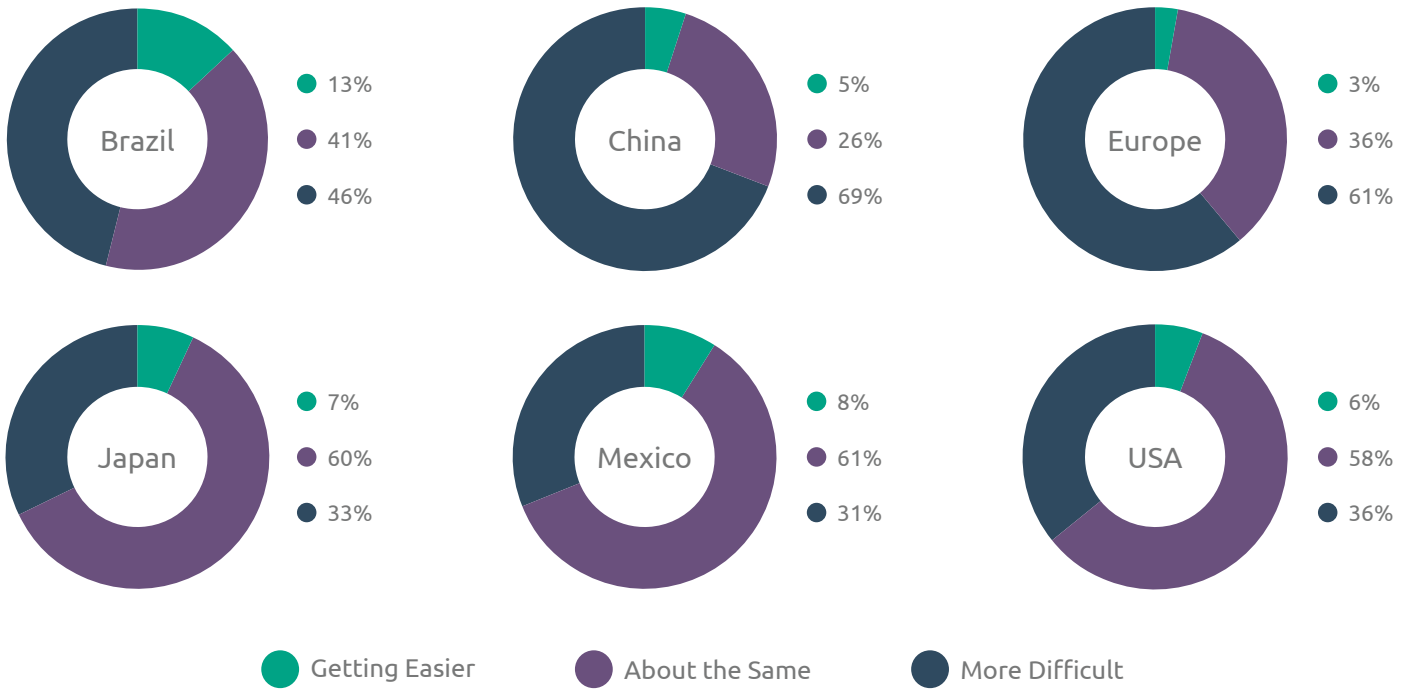
The chart below shows the relative market share of the top Notified Bodies (NB). These seven Notified Bodies - plus additional companies such as UL, DNV and TUV NORD - control 80% of the medical device certification and auditing business. Market share among these companies varied significantly by region.



Based on 1,197 responses from QA/RA professionals only. We made every effort to eliminate duplicate answers from the same company.

Based on your experience, do you think the current process of obtaining regulatory approval for a medical device or IVD in these markets is easier or more difficult than it was a few years ago?

Just a few short years ago, Europe was considered the middle benchmark to which the difficulty of other regulatory processes was compared. Some were harder, some were easier. Times have changed. The introduction of stringent clinical data requirements, and increasing demands by Notified Bodies, have made CE Marking significantly more difficult to obtain and maintain. Not surprisingly, China retains its reputation as the most onerous market to enter according to QA/RA professionals* worldwide, primarily due to the ongoing barrage of new regulations released by the CFDA in recent years. One thing is certain: medical device regulatory professionals will remain in high demand well into 2020 when the MDR comes into force.



Country	Getting Easier		About the Same		More Difficult	
	JAN 2016	JAN 2017	JAN 2016	JAN 2017	JAN 2016	JAN 2017
Brazil	10%	13%	47%	41%	42%	46%
China	5%	5%	26%	26%	69%	69%
Europe	5%	3%	60%	36%	35%	61%
Japan	6%	7%	62%	60%	32%	33%
Mexico	7%	8%	67%	61%	26%	31%
USA	6%	6%	64%	58%	30%	36%

We only asked this question of QA/RA professionals and only accepted responses from people with experience in the market. We received between 640 responses (Mexico) and 1,201 responses (Europe) to this question in this year's survey.

Who took this survey?

More than 3,000 people worldwide took the 2017 medical device industry outlook survey.

North America
41%

Europe
33%

Asia Pacific
19%

Other
7%

What is your primary area of responsibility within your company?

- **18%** President/CEO/COO/ Managing Director
- **57%** Regulatory/Quality/Clinical
- **9%** Engineering/R&D/ Product Management
- **12%** Sales/Marketing/Business Development/Export
- **4%** Other

Does your company design or manufacture medical devices or IVDs?

Yes, medical devices only
65%

Yes, medical devices and/or IVDs
16%

19% of survey takers do not design/manufacture medical devices or IVDs.

How many people work for your company/organization worldwide?

Employees 1-9	Employees 10-49	Employees 50-249	Employees 250-999	Employees 1000+
16%	25%	23%	12%	24%

Are you a member of the senior management team?

YES **27%** | **73%** NO

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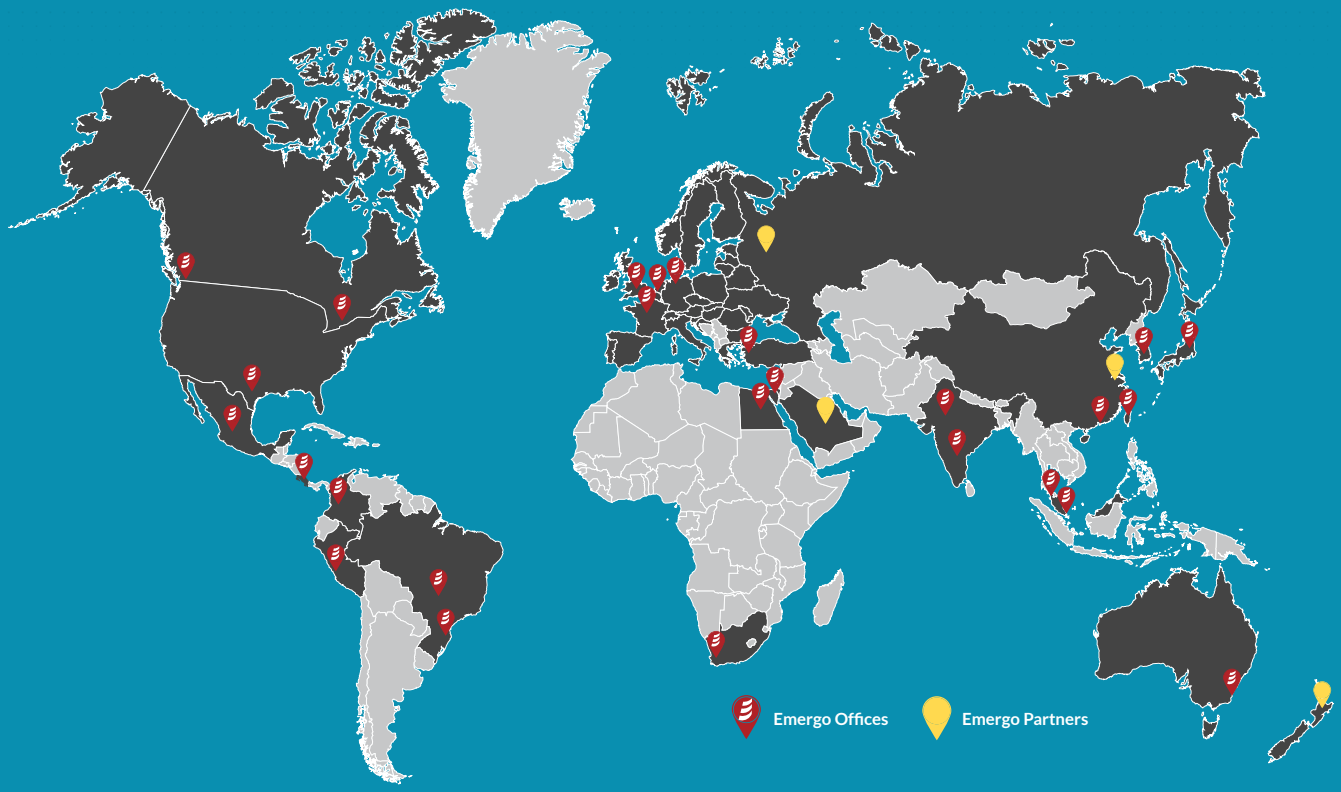

Survey Methodology

Our 2017 Global Medical Device Industry Outlook survey was conducted between December 5, 2016 and January 16, 2017. A total of 3,075 medical device industry professionals participated.

The survey was emailed to 36,000 people in a database list maintained by Emergo, and also promoted via our weekly RADAR newsletter. Respondents were self-selecting but only one response per participant was allowed.

Many of the questions were only asked of people working for medical device manufacturers and most specific questions excluded distributors, consultants and industry suppliers. Where necessary, we filtered responses so only one answer was accepted per company.

Due to the nature of our business, QA/RA professionals make up a much higher percentage of respondents than otherwise represented in the industry as a whole. We excluded QA/RA respondents from some questions but overall results should be interpreted with this in mind.

Our intention in conducting this annual survey is to provide a high-level snapshot of the industry's current climate, as well as its prospects over the coming year. If you would like permission to publish graphs or content cited in this report, please email marketing@emergogroup.com.