

GLOBAL MEDICAL DEVICE INDUSTRY OUTLOOK FOR 2018

Based on a survey of more than
4,200 industry professionals

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a UL company

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Executive Summary: January 2018

Overall, it appears as though 2017 was more so good than great for medical device companies. Survey respondents reported lower sales increases compared to last year's results—but fewer firms also reported sales decreases versus the previous year.

These more modest performance results help explain lower growth expectations for all markets heading into 2018. Respondents' outlooks for US and European market prospects remain more optimistic than for emerging markets, but substantially less so than for 2017.

Implementation of sweeping new medical device and IVD regulations in Europe continues to impact CE Mark certificate holders and Notified Bodies, eliciting more cautious approaches to this market from manufacturers.

In the US, the Trump administration has touted reduced and streamlined FDA regulatory processes, but ongoing attempts to repeal or reduce the scope of the Affordable Care Act and related federal healthcare programs have added uncertainty for market registrants.

Emerging markets continued providing their own mixed bags of opportunities and challenges in 2017, as well. But efforts by regulators in China, Brazil and India to formalize registration pathways and ease some market entry requirements may drive more interest from manufacturers in 2018.

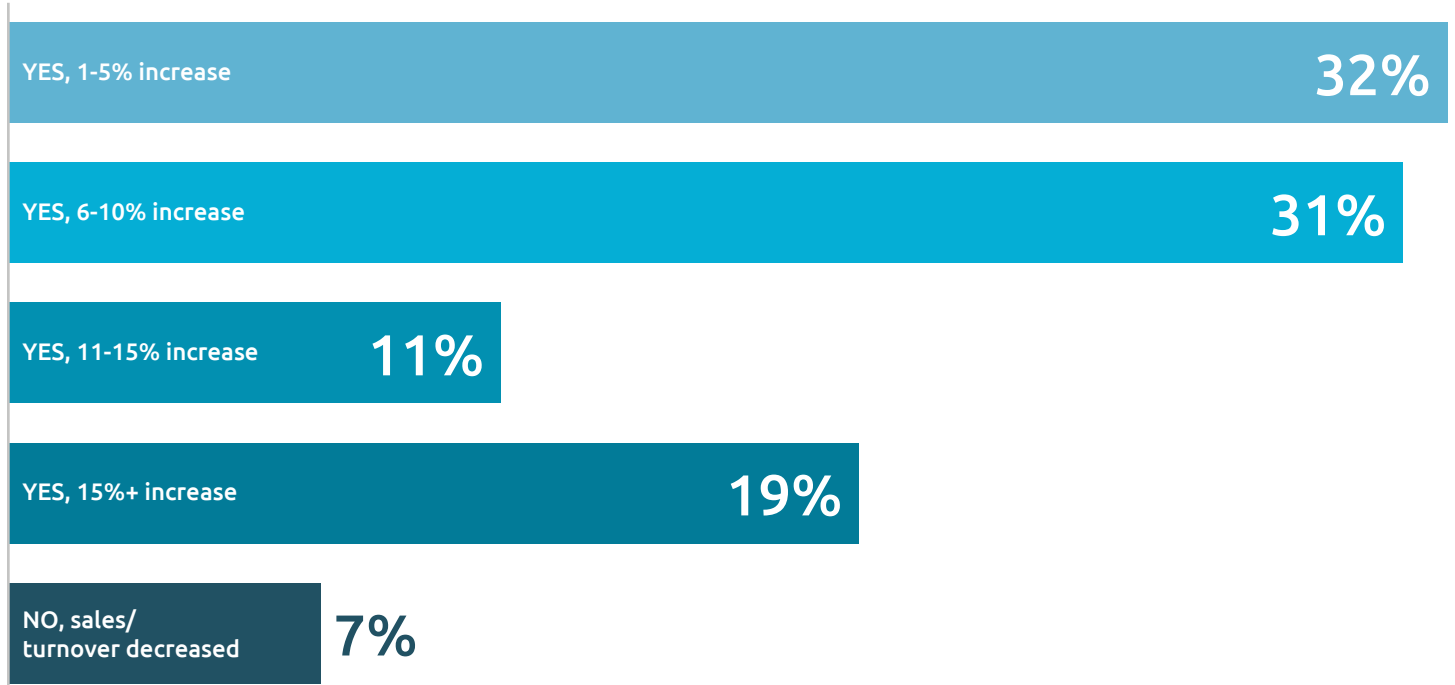
Key takeaways from our 2018 survey:

- About 60% of companies reported sales increases of 10% or less.
- Companies are still bullish on US and European market growth, but growth expectations for markets overall are down from last year.
- More than 65% of firms see Europe as a more difficult market given the transition to the MDR and IVDR...
- ...but more than 40% of firms also anticipate strong sales growth in Europe for 2018.
- Regulatory changes and new product development are challenges for companies of all sizes.

As ever, larger and more lucrative medical device markets also feature more complex regulatory requirements, so manufacturers have their work cut out for them in terms of realizing their commercialization goals. Despite near-term challenges, however, favorable global demographic trends and health demand for medical devices and technology will continue to bolster the industry in 2018.

Did (or do you expect) your company to experience an increase in worldwide sales/turnover in 2017?

2017 saw more modest sales increases for most respondents compared to 2016. Whereas a full third of companies reported sales increases of more than 10% in last year’s survey, more than 60% of firms this year indicated growth rates of 10% or less. But, sales decreases occurred at fewer companies (seven percent) in 2017 than in 2016 (10%).



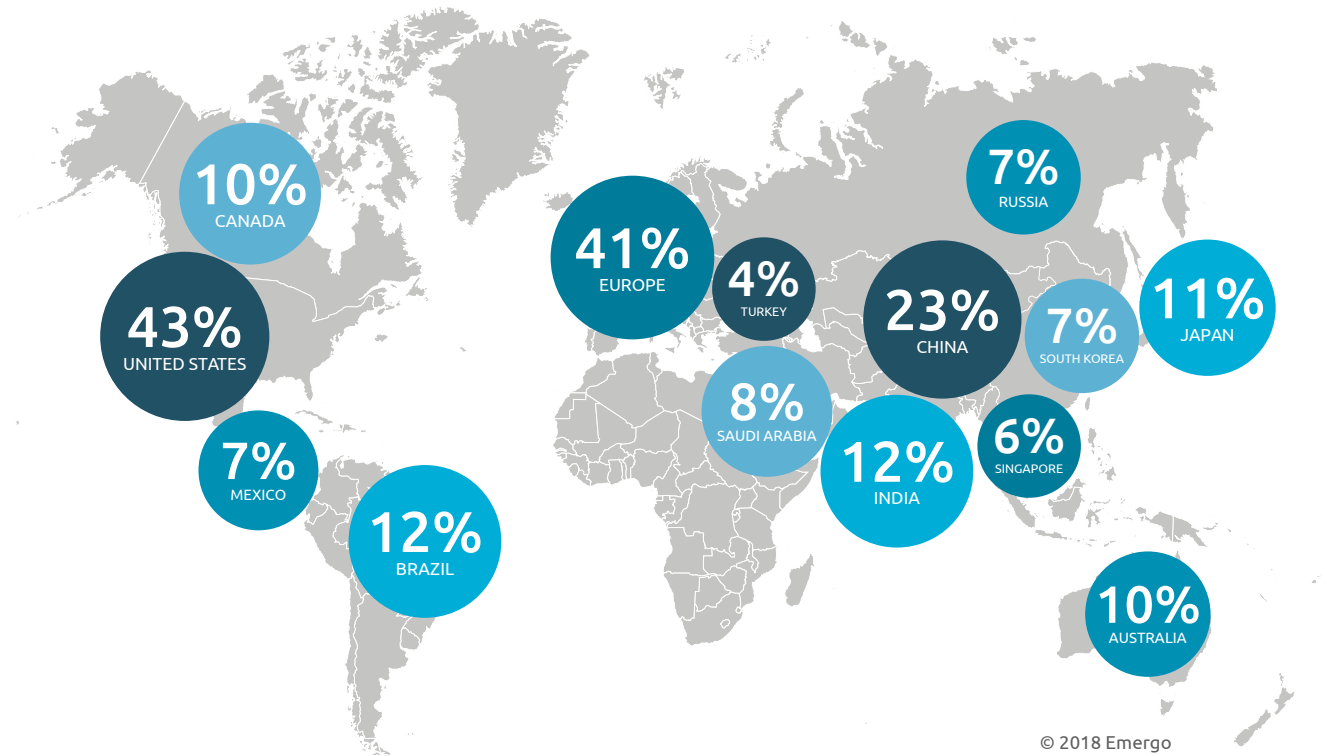
Sales/turnover results for 2017 segmented by company size					
Number of Employees	YES, 1-5% increase	YES, 6-10% increase	YES, 11-15% increase	YES, 15%+ increase	No, sales/turnover decreased
1-9	29%	21%	9%	28%	13%
10-49	30%	25%	9%	25%	11%
50-249	30%	30%	12%	20%	8%
250-999	32%	34%	15%	12%	7%
1000+	39%	38%	11%	10%	2%

Companies with less than 50 employees were more likely to see sales decreases last year, but also saw increases of 15% or more at a higher rate than larger companies.

Based on 1,992 responses.

Which markets do you expect to produce the strongest growth in sales/turnover for your company in 2018?

As in previous years, survey respondents expressed higher expectations for the US and Europe than other countries, but optimism decreased across established and emerging markets alike for 2018. Declines of roughly 15% and 10% for US and European market growth expectations, respectively, may reflect lower reported performance numbers from 2017. BRIC and other emerging markets also saw declines in 2018 expectations, but at less dramatic rates.



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Noteworthy changes between 2017 and 2018

Market	JAN 2017	JAN 2018
Brazil	17%	12%
China	33%	23%
Europe	51%	41%
India	18%	12%
Mexico	11%	7%
Saudi Arabia	13%	8%
USA	60%	43%

Based on 3,398 responses.

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

Asia remains the heavy favorite among respondents in terms of long-term growth prospects—even though companies indicated lower 2018 expectations for markets such as China and India. Also as in previous years, North American and European markets continue to be seen as more stable but with less high growth potential.



AFRICA



16%



20%



23%



ASIA



52%



22%



3%



EUROPE



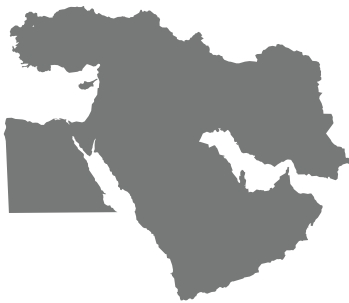
17%



47%



19%



MIDDLE EAST



23%



34%



12%



NORTH AMERICA



23%



45%



11%



SOUTH AMERICA



21%



35%



13%



High Growth Potential



Average Growth Potential

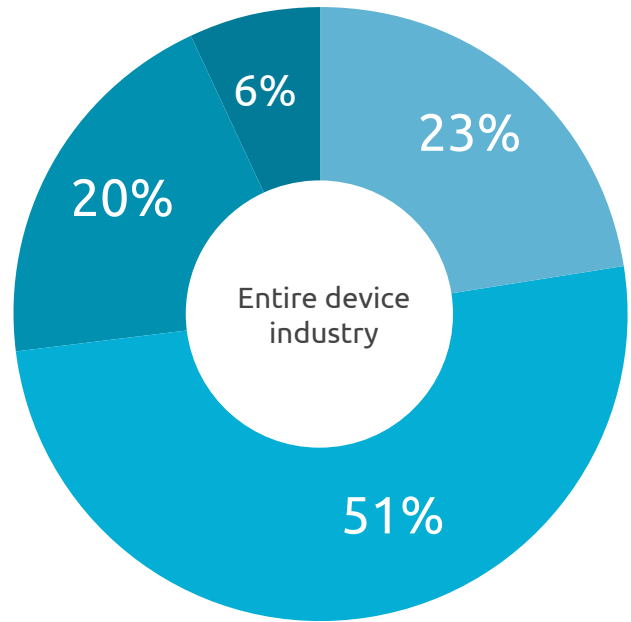
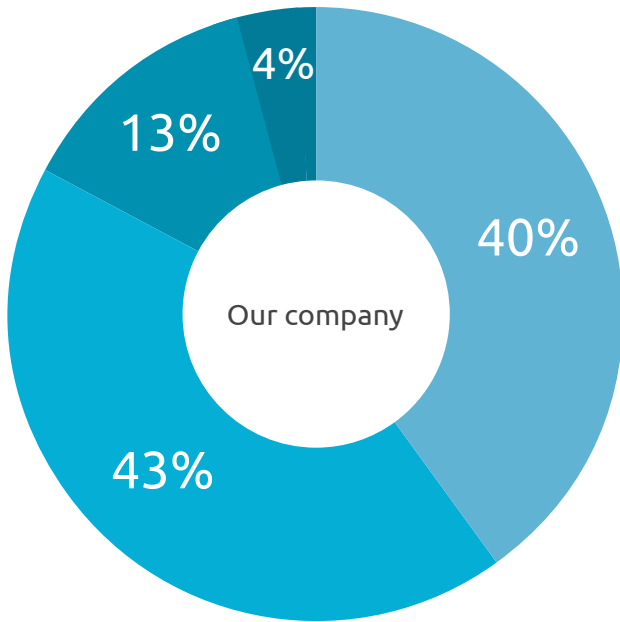


Low Growth Potential

Based on 3,968 responses.

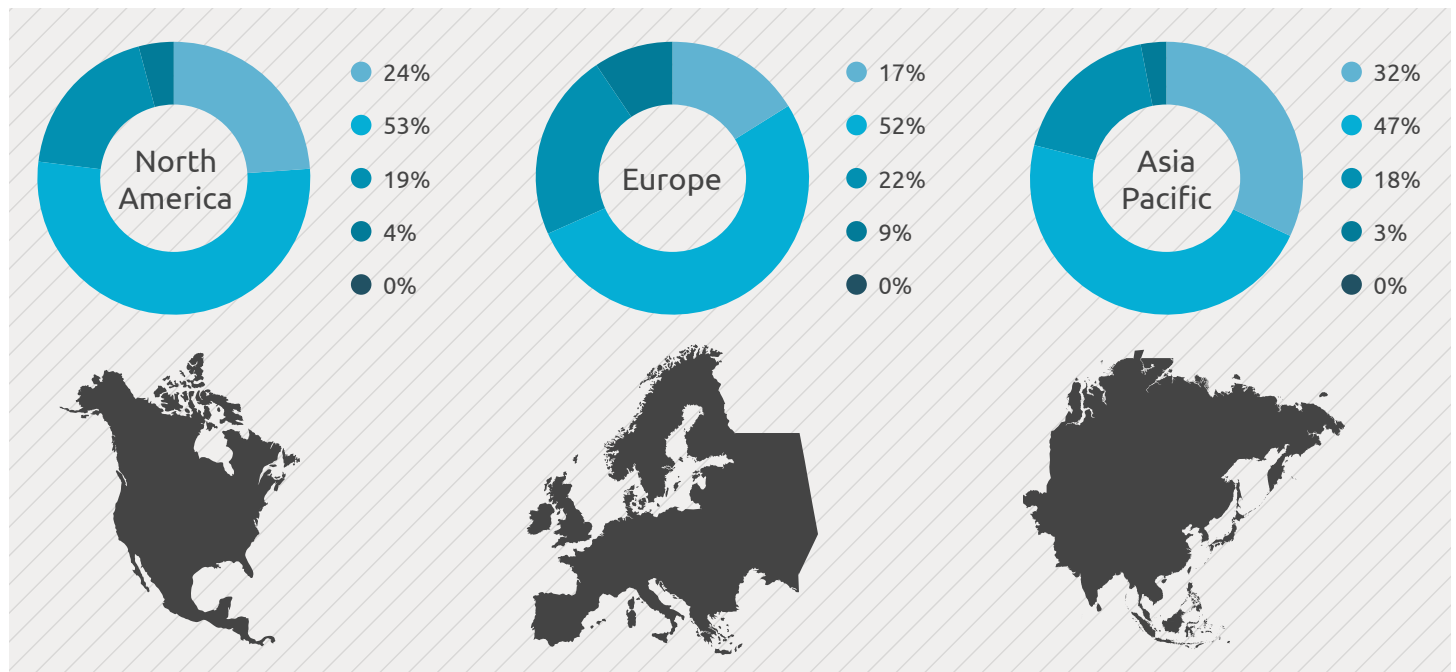
When you think about your company and the entire medical device industry, how do you feel about 2018?

Overall, companies expressed significantly more optimism for their own 2018 prospects than for the industry as a whole—40% of respondents have a very positive outlook for their own firms versus 23% for the entire device industry. These percentages haven't changed from our 2017 survey.



● Very POSITIVE
 ● Somewhat POSITIVE
 ● NEUTRAL
 ● Somewhat NEGATIVE
 ● Very NEGATIVE

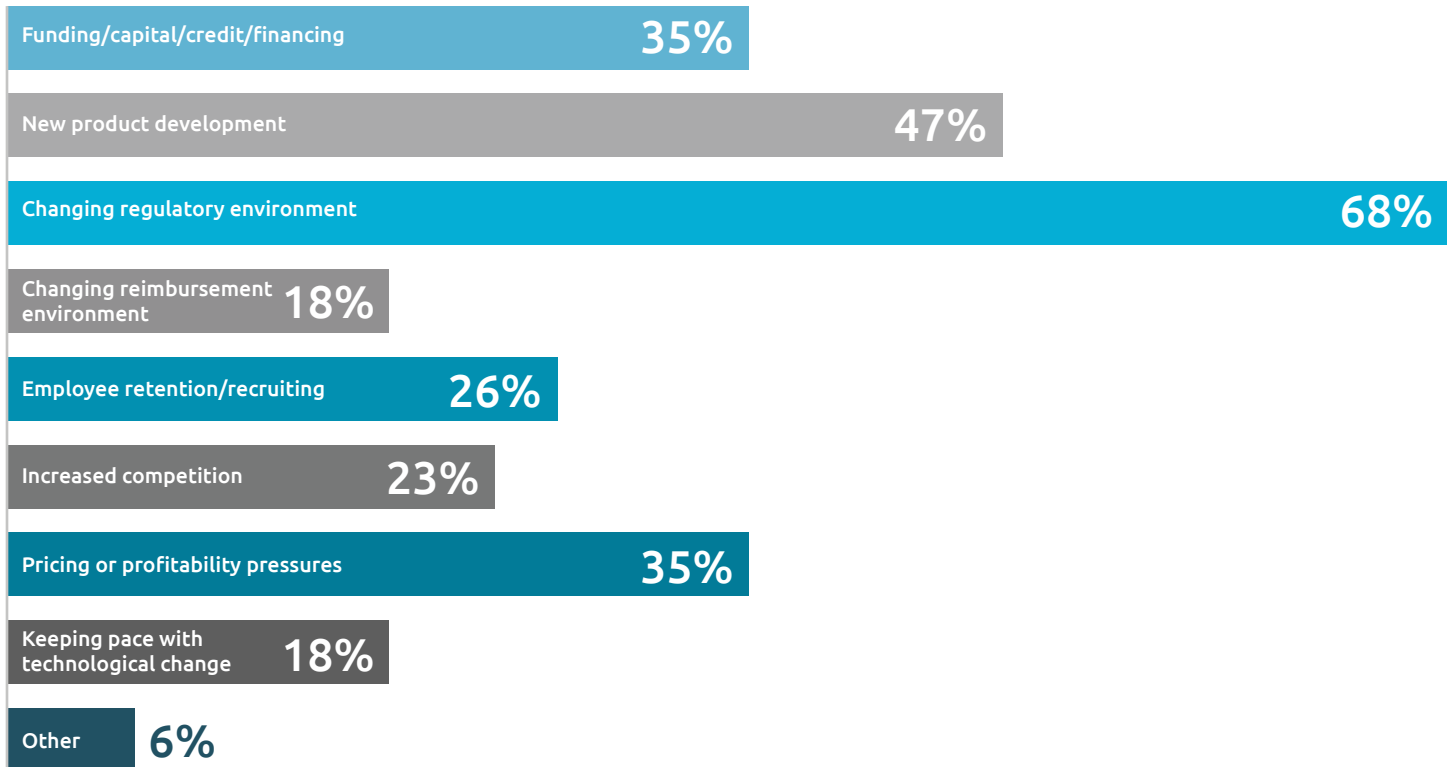
How medical device companies in each region feel about the industry in 2018:



Based on 3,942 responses.

What are the biggest challenges you face?

This question was directed only to respondents who serve as senior managers and executives at their firms. By now, it comes as no surprise that regulatory changes continue to be the top business challenge for firms of all sizes. But higher percentages of companies of all sizes cited this challenge compared to 2017; 56% of firms with less than 10 employees reported regulatory changes as a major challenge this year, up from 45% in last year’s survey. Massive regulatory changes underway in Europe play a key factor in this shift.

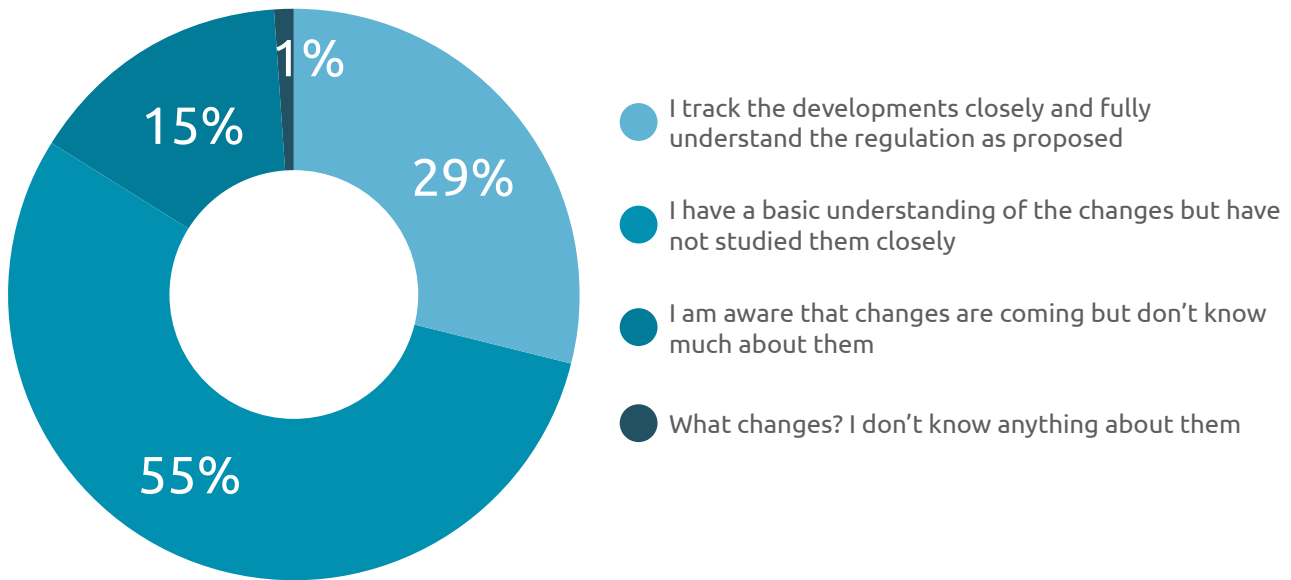


Results segmented by number of employees									
Number of Employees	Funding & capital	Product development	Regulatory changes	Reimbursement environment	Employee retention	Increased competition	Pricing pressure	Technological changes	Other
1-9	54%	44%	56%	15%	14%	14%	25%	12%	7%
10-49	38%	45%	68%	17%	25%	20%	35%	13%	5%
50-249	23%	51%	76%	20%	34%	31%	43%	27%	4%
250-999	14%	50%	73%	20%	40%	24%	41%	20%	7%
1000+	11%	52%	79%	28%	39%	47%	41%	31%	4%

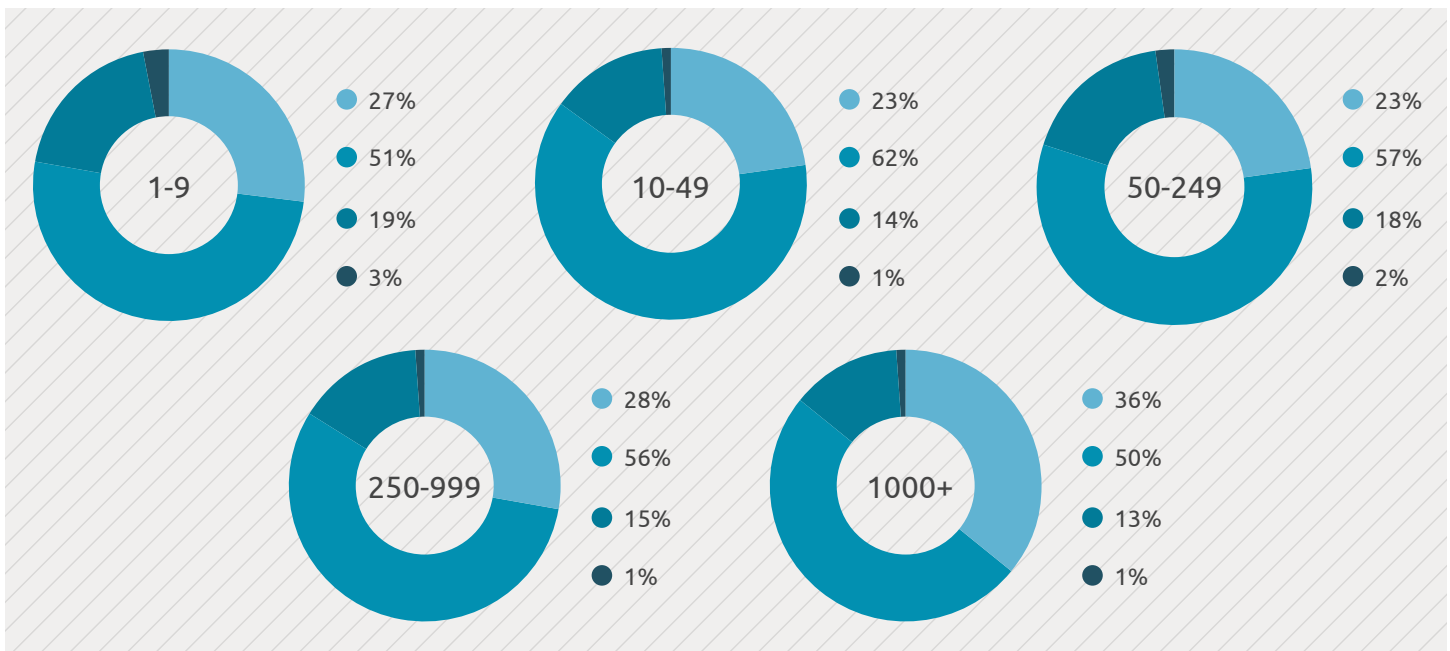
Based on 1,085 responses.

In 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 number of companies closely tracking MDR and IVDR developments has increased slightly from last year—29% of firms in 2018 versus 21% in 2017—but a majority of respondents (55%) still claim only a basic understanding of the new Regulations. Thus, most firms either have more work to do before 2020 to fully understand MDR and IVDR compliance—or rely on third-party consultants for support. Unlike in our 2017 survey, half of even the largest firms (those with 1000 or more employees) reported basic rather than full understanding of the European regulatory changes.



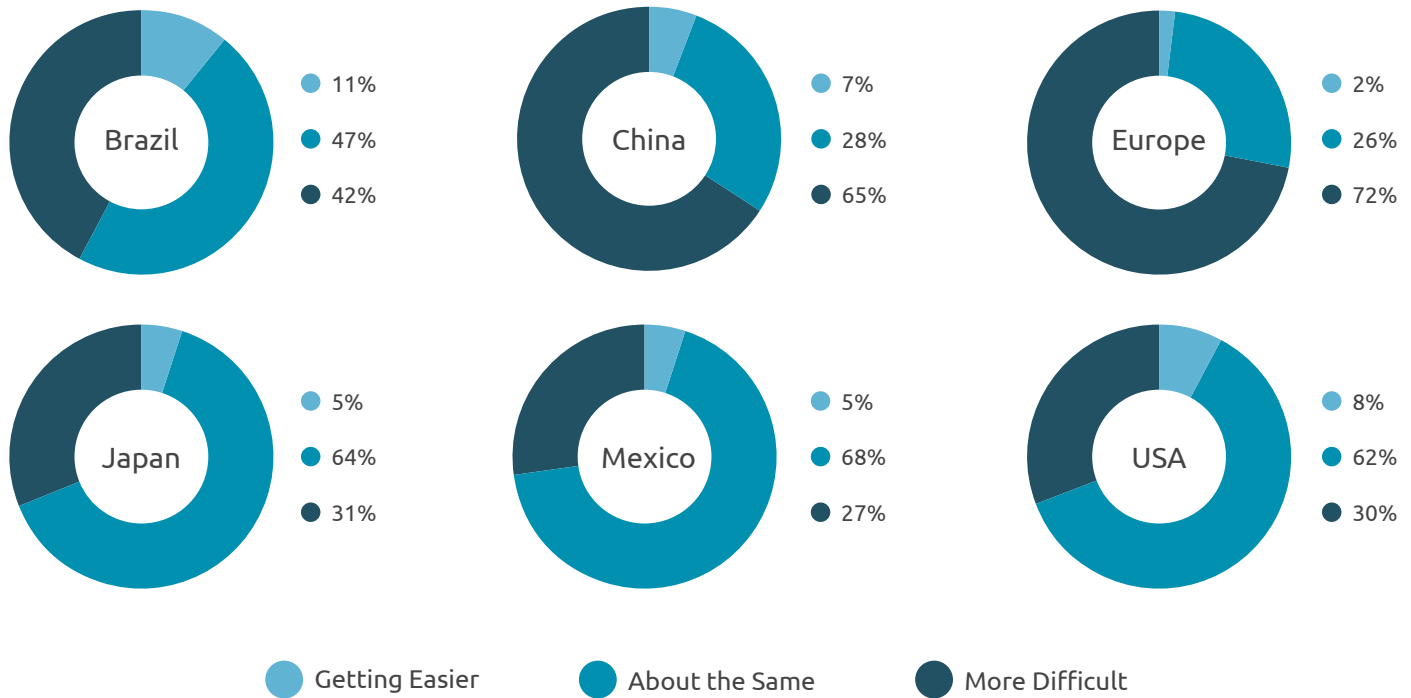
Results segmented by number of employees



Based on 2,285 responses.

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?

The percentage of respondents citing greater difficulty obtaining CE Marking in Europe grew dramatically in our 2017 survey, and has increased even more so this year. The ramifications of MDR and IVDR compliance along with business challenges for Notified Bodies are clearly driving these numbers. Firms also expect the Chinese market to pose more challenges going forward, but moves by the China Food and Drug Administration to relax testing and clinical trial requirements may eventually ease some registrants' market entry efforts.

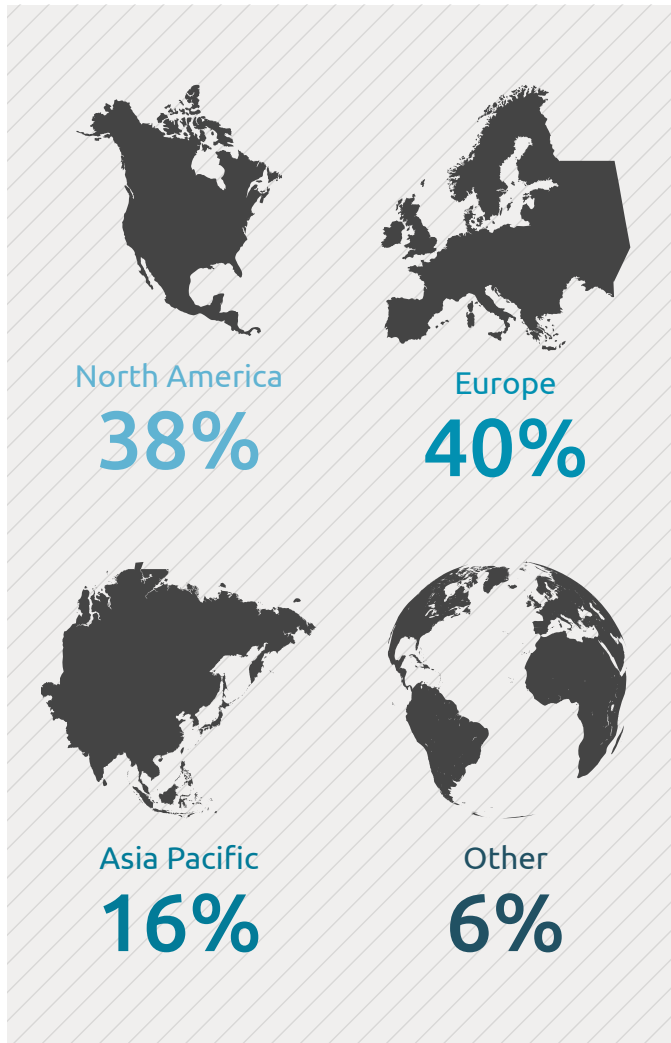


Country	Getting Easier		About the Same		More Difficult	
	JAN 2017	JAN 2018	JAN 2017	JAN 2018	JAN 2017	JAN 2018
Brazil	13%	11%	41%	47%	46%	42%
China	5%	7%	26%	28%	69%	65%
Europe	3%	2%	36%	26%	61%	72%
Japan	7%	5%	60%	64%	33%	31%
Mexico	8%	5%	61%	68%	31%	27%
USA	6%	8%	58%	61%	36%	30%

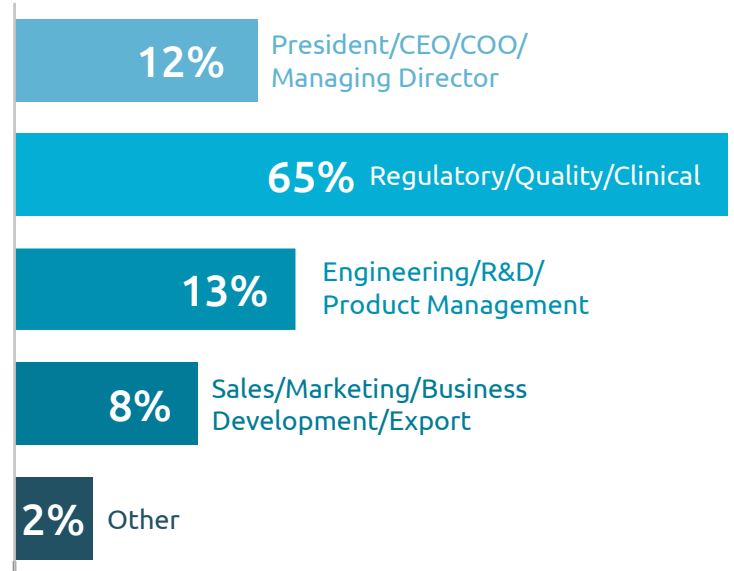
We only asked this question to QA/RA professionals, and only accepted answers from respondents with experience in each market. We received between 965 responses (Mexico) and 1,994 responses (Europe).

Who took this survey?

More than 4,200 people worldwide took our 2018 medical device industry outlook survey.



What is your primary area of responsibility within your company?



Does your company design or manufacture medical devices or IVDs?



17% of survey takers do not design/manufacture medical devices or IVDs.

How many people work for your company/organization worldwide?



Are you a member of the senior management team?



Survey Methodology

Our 2018 Global Medical Device Industry Outlook survey was conducted between December 1, 2017 and January 22, 2018. A total of 4,282 medical device industry professionals participated.

The survey was emailed to 65,000+ people in a database list maintained by Emergo, and also promoted via our RADAR weekly 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 that 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.