

A photograph of an operating room with surgical lights, monitors, and medical equipment. A dark blue semi-transparent box is overlaid on the left side of the image, containing white text.

# Global Medical Device Industry Outlook for 2021

Based on a survey of more than  
1,600 industry professionals

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For more information contact:  
**Stewart Eisenhart**  
EmergoMarketing@ul.com

EmergobyUL.com



by UL

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A photograph of four business professionals in a meeting room. Three people are leaning over a table, looking at documents and a laptop. A fourth person is partially visible on the left. The scene is brightly lit, likely from a window in the background.

# Executive Summary

Our 2021 survey results do not deviate significantly from our results in previous years. Normally such findings would be unsurprising to longtime readers of our reports. But given the global economic turmoil of the past 12 months due to the coronavirus pandemic, the consistency of these results are remarkable in that it demonstrates the industry's resilience.

The pandemic did negatively impact business in 2020 for most survey respondents—but nearly 30% of firms reported increased business stemming from the health crisis, painting a more complex picture of how the industry has been affected. In terms of overall performance for 2020, companies reported only a slight two-percent uptick in sales declines.

Although regulatory challenges remain front and center for a majority of this year's survey participants, one notable effect of the coronavirus pandemic was the decision by European regulators to delay the Medical Devices Regulation's (MDR) final date of application by a full year, to May 2021. This delay may have provided manufacturers enough of a cushion to better prepare for full MDR compliance, but time will tell. (Our next survey later this spring will break out and more closely examine various regulatory issues facing medical device and IVD manufacturers, including MDR compliance.)

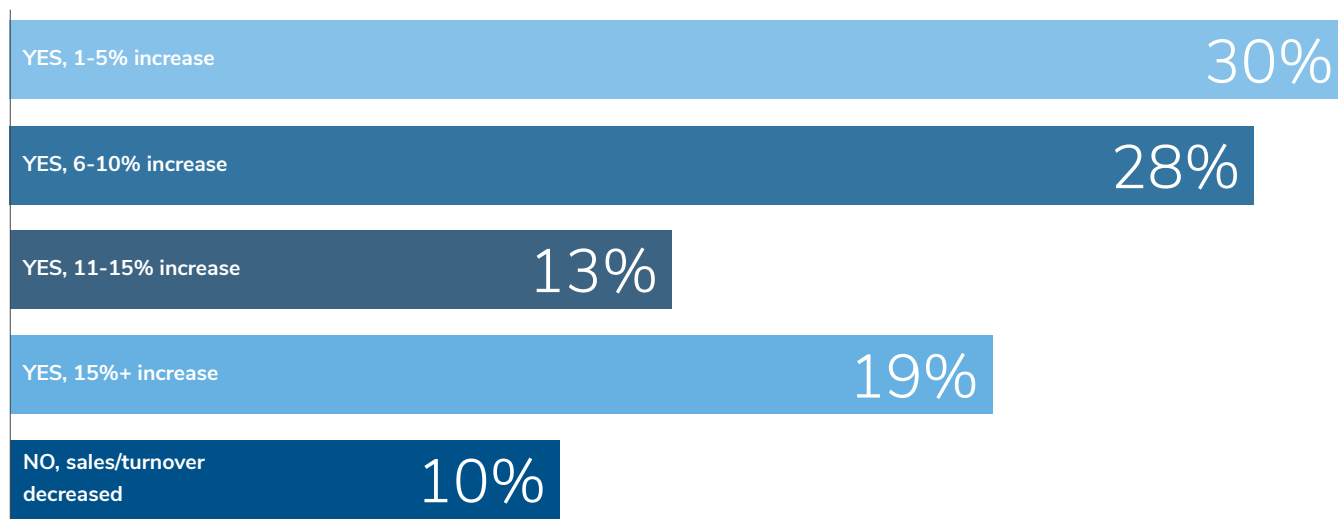
Regarding market growth expectations and outlooks, our 2021 survey respondents continue their long-term optimism regarding Asia; in the meantime, however, companies are relying even more so on North American and European markets for steady (if not necessarily stellar) growth.

## Key findings from our 2021 survey:

- More than 18% of firms reported sales increases of 15% or more over the past 12 months, but the number of firms reporting sales declines also ticked up slightly from eight percent in 2020 to more than 10% this year.
- More than half of companies saw their business decline somewhat or substantially due to the coronavirus pandemic.
- Manufacturers' faith in US and European markets has increased over the near term, but long-term expectations for Asian markets remain very high.
- Changing regulatory environments remain companies' biggest business challenge, but less so than in previous years as issues such as funding, pricing pressures and product development have become more pronounced.
- Larger manufacturers are adopting automated regulatory affairs and quality assurance (RA/QA) technologies at a higher rate than small- and mid-sized firms.

## Did you (or do you) expect your company to experience an increase in worldwide sales/turnover in 2021?

Medical device and IVD companies indicate stable growth rates compared to 2020, with the exception of firms reporting sales increases of 15% or higher. This year’s results found more than 18% of respondents seeing such growth, versus 14% for our 2020 survey. However, larger firms (those with 250 or more employees) reported higher rates of sales decreases compared to their performance in 2020 than smaller companies; across the board, the number of firms reporting sales decreases ticked up slightly from last year.

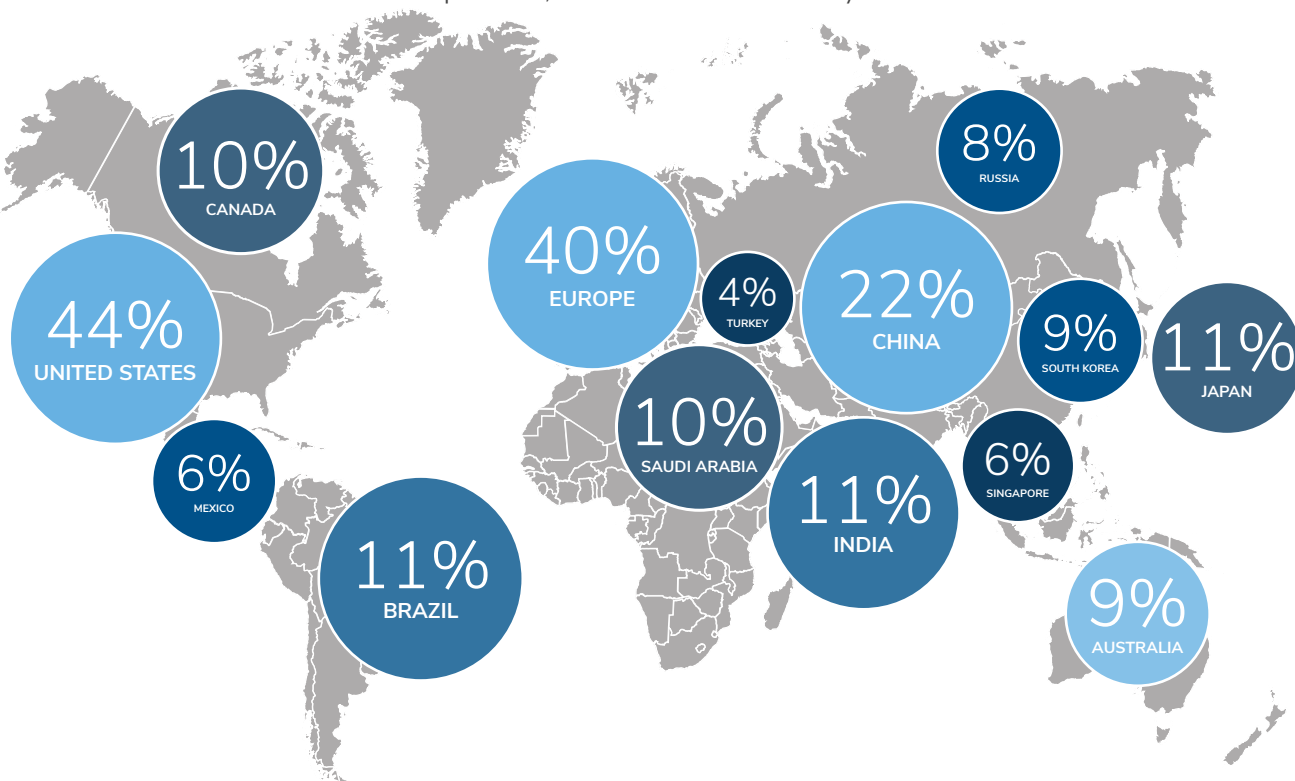


Sales/turnover results for 2021 segmented by company size					
Number of Employees	YES, 1-5% increase	YES, 6-10% increase	YES, 11-15% increase	YES, 15%+ increase	NO, sales/turnover decreased
10-49	23%	28%	10%	26%	13%
50-249	32%	30%	14%	13%	11%
250-999	33%	29%	16%	16%	6%
1,000+	38%	32%	12%	11%	7%










Based on 1,087 responses.

## Which markets do you expect to produce the strongest growth in sales/turnover for your company in 2021?

The most significant shifts in growth expectations this year compared to our 2020 results were toward the US and European markets. The number of respondents expecting strong US market growth increased from 40% last year to 44% for 2021, while expectations for growth in Europe increased from 37% of firms in 2020 to 40% now. Growth expectations for the Chinese market remained stable at 22% of respondents, identical to our 2020 survey results.



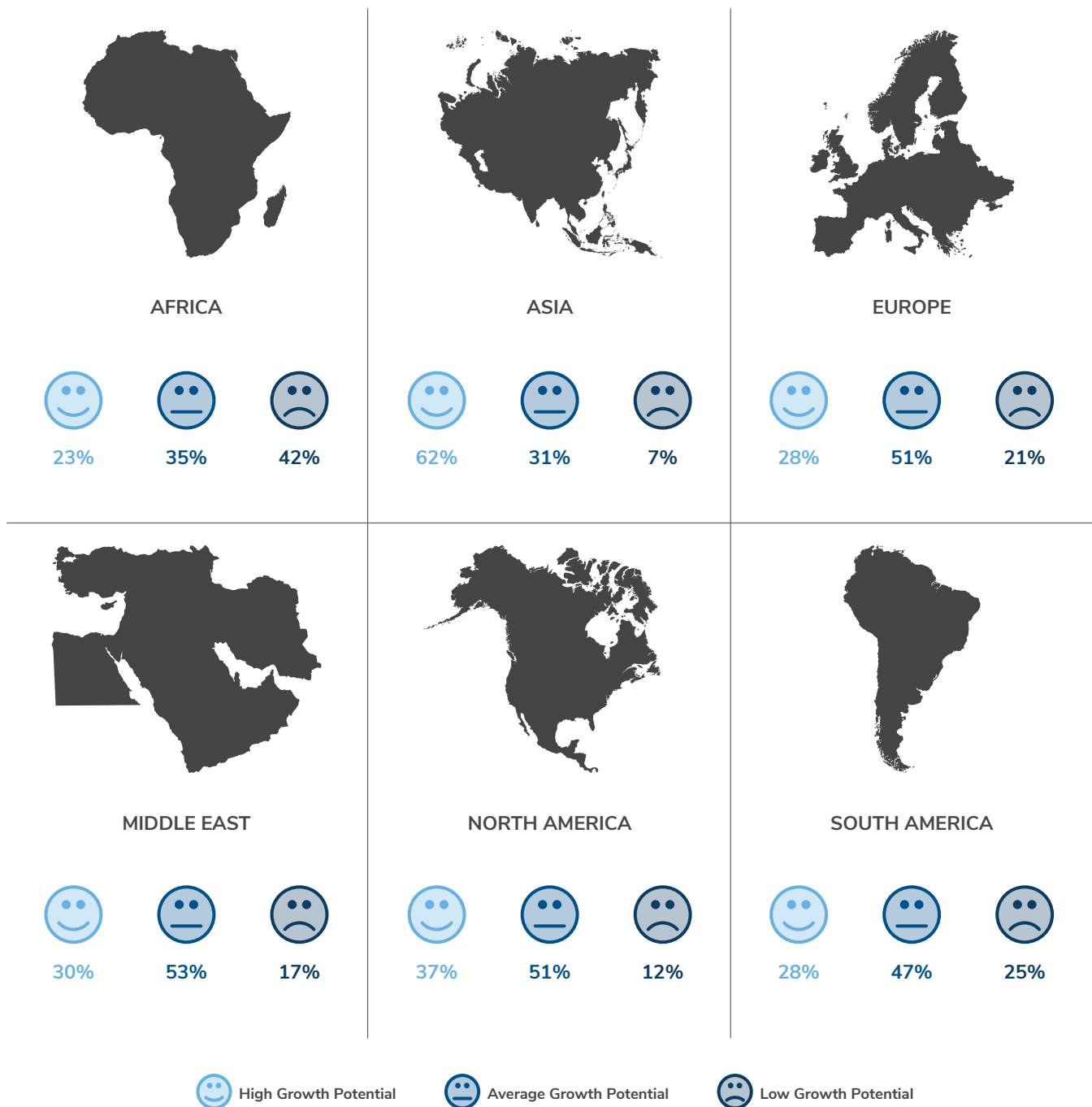
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Noteworthy changes between 2020 and 2021			
Market		Mar 2020	Mar 2021
 Australia		8%	9%
 Brazil		11%	11%
 China		22%	22%
 Europe		37%	40%
 India		12%	11%
 Japan		11%	11%
 Mexico		7%	6%
 Russia		7%	8%
 USA		40%	44%

Based on 1,110 responses.

## What do you think about the growth potential for medical device and IVD sales in these regions over the next five years?

More than 60% of our 2021 survey respondents see Asian markets as having high five-year growth potential, in keeping with prior years' numbers but down ever so slightly from our 2020 results (65% of firms). Firms are also more bullish on Europe and North America as high-growth markets compared to 2020, on the other hand. Despite—or because of—major developments including the ongoing coronavirus pandemic and massive regulatory changes in the European Union, more manufacturers may see higher potential in safer bets.

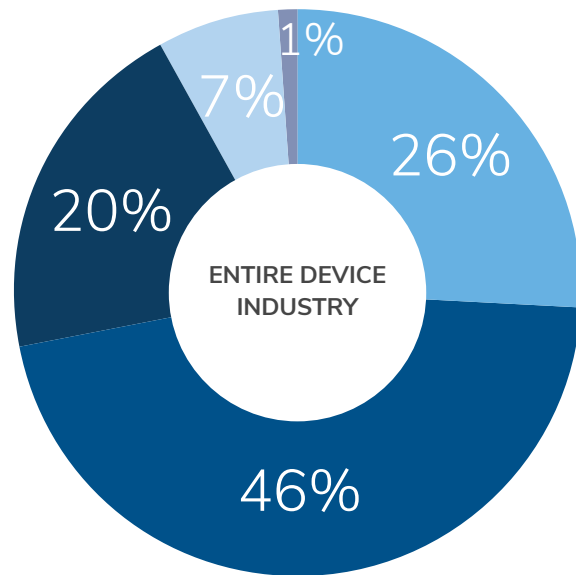
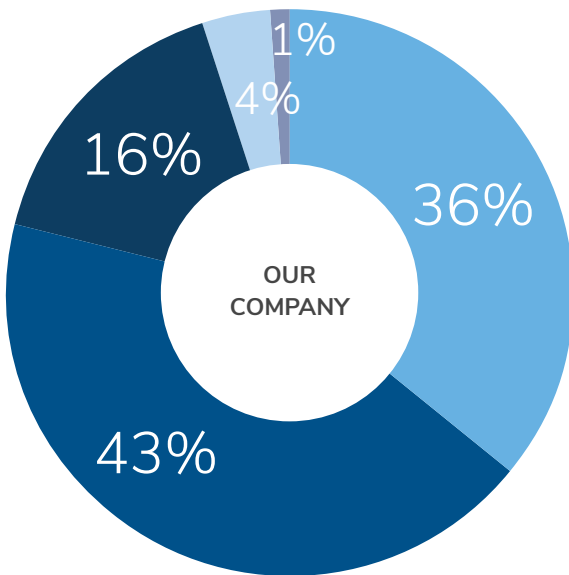


Based on 1,422 responses.

## When you think about your company and the entire medical device industry, how do you feel about 2021?

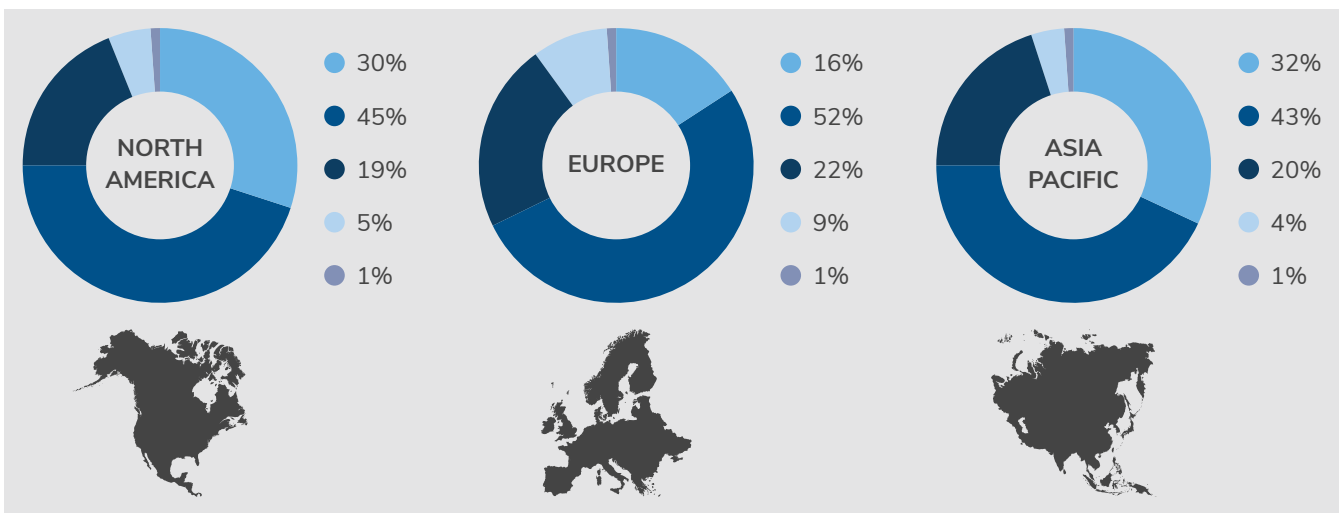
“Cautious optimism” is how we’ve typically described results for this question in previous years. For 2021, however, respondents appear slightly more optimistic than cautious—at least in terms of how they view the medical device and IVD industry as a whole. The number of firms expressing very positive outlooks for their industry increased six points, from 20% last year to 26% for 2021.

In terms of regional differences, respondents based in Europe remain less likely than their North American and Asian counterparts to take an extremely positive outlook for either their own firms or their industry, in keeping with our 2020 findings.



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

## How medical device companies in North America, Europe and Asia feel about their industry in 2021:



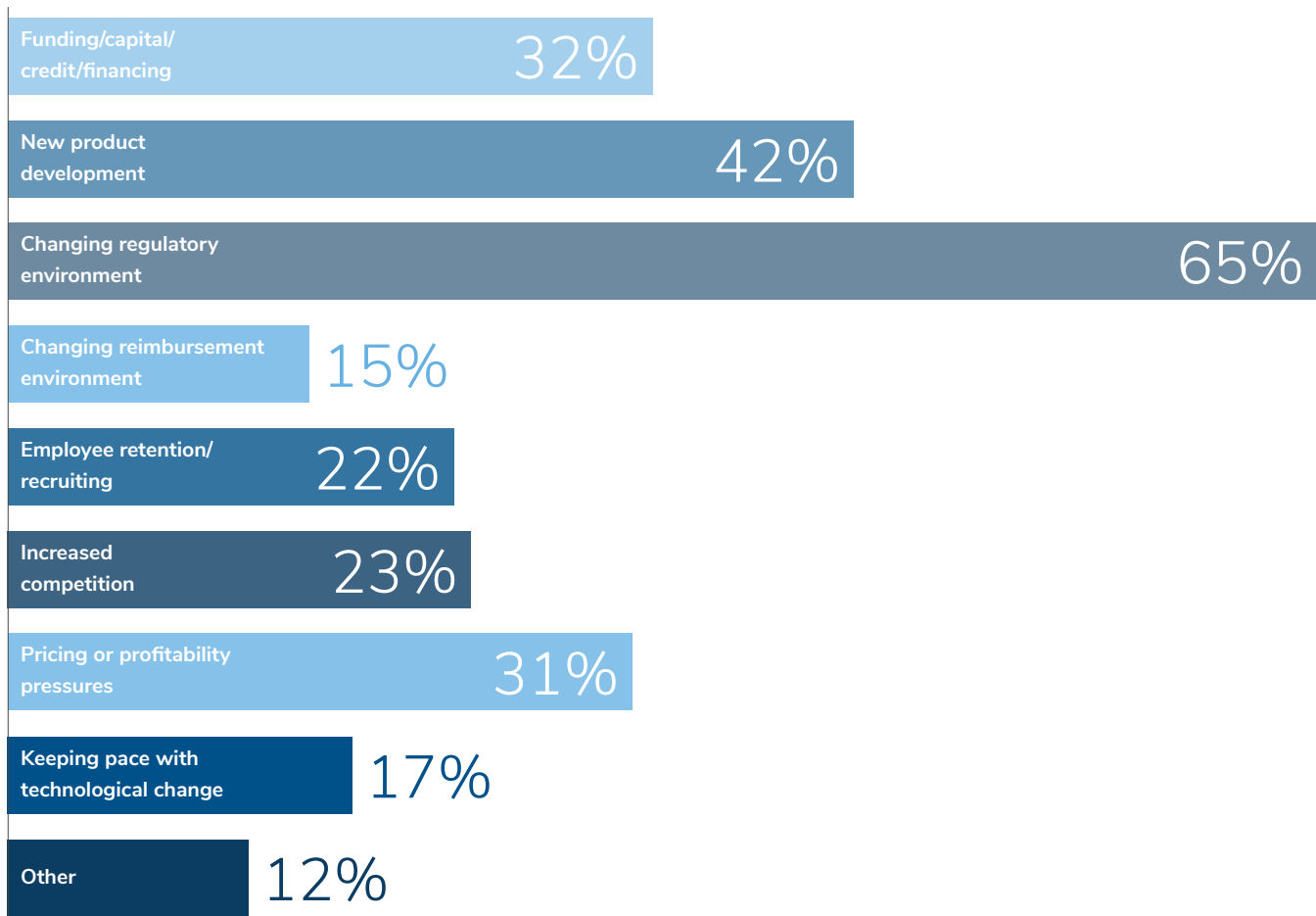
Based on 1,407 responses.

## What are the biggest challenges you face?

Although changing regulatory environments remain the most frequently cited business challenge among our 2021 survey participants, only 65% of companies this year did so versus 74% of firms in 2020. Given broader economic downturns brought about by the coronavirus pandemic, funding and capital challenges have also increased for more firms.

Significant regional differences were also apparent in our 2021 results:

- Funding and capital challenges were more pronounced among North American respondents (40% of firms).
- Regulatory challenges were cited most highly among European companies (74% of firms), which makes sense considering the MDR and IVDR set for full implementation in 2021 and 2022, respectively.
- A higher percentage of Asian companies (32%) identified competition as a major challenge, as well as pricing and profitability pressure (32% of firms).



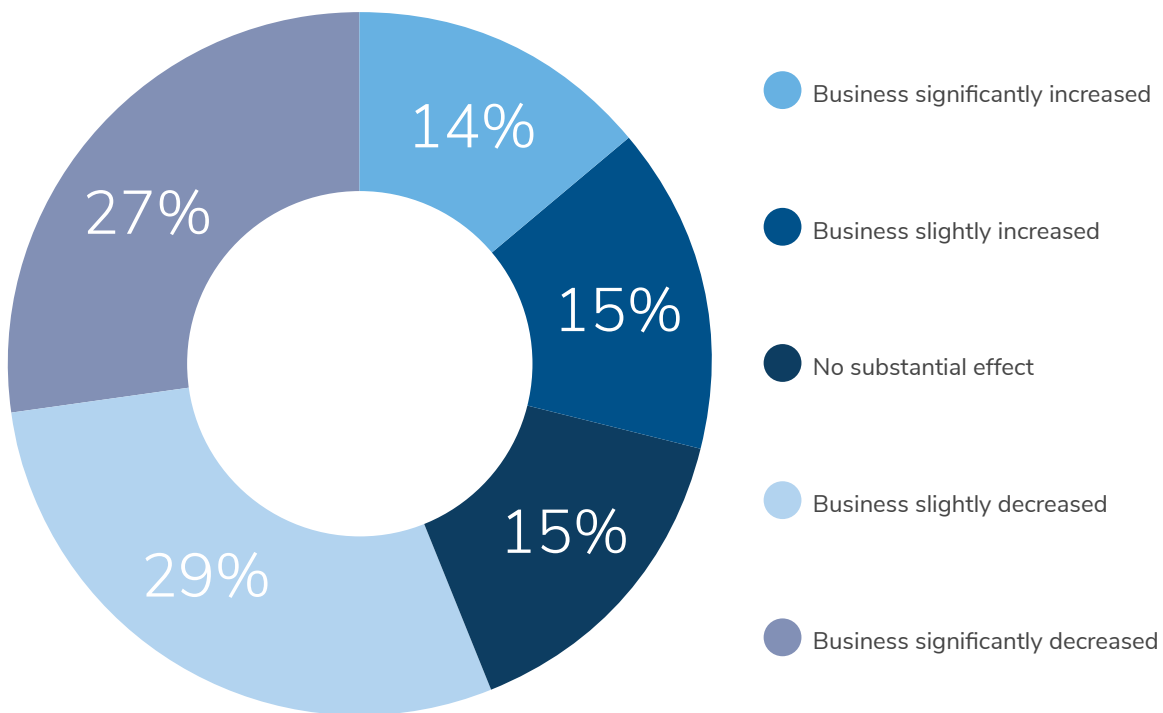
Based on 510 responses.



## How did the coronavirus pandemic affect your business in 2020?

Overall, the ongoing coronavirus pandemic has had a negative impact on medical device and IVD manufacturers' operations for 2020, with 56% of survey respondents reporting slight or significant declines for their businesses. Such effects were less pronounced for the largest companies, however:

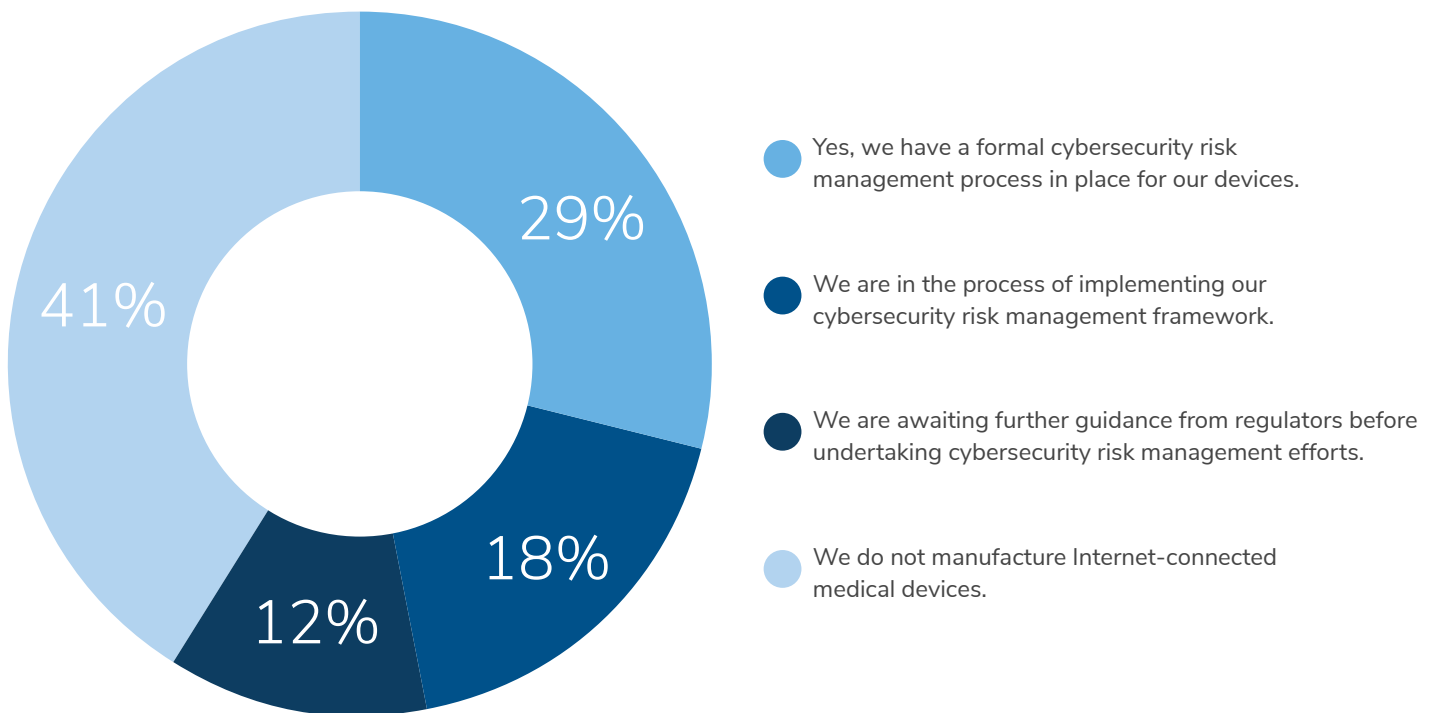
- About 23% of firms with 1,000 or more employees reported significant business increases due to the pandemic.
- Our smaller respondents (firms with less than 50 employees) reported significant business decreases at a rate of nearly 30%.
- Mid-sized firms with between 250 and 1,000 employees incurred the highest rate of pandemic-related business decreases, with 64% of these companies indicating either slight or significant losses for 2020.



Based on 507 responses.

## Have you established risk management processes to address cybersecurity issues?

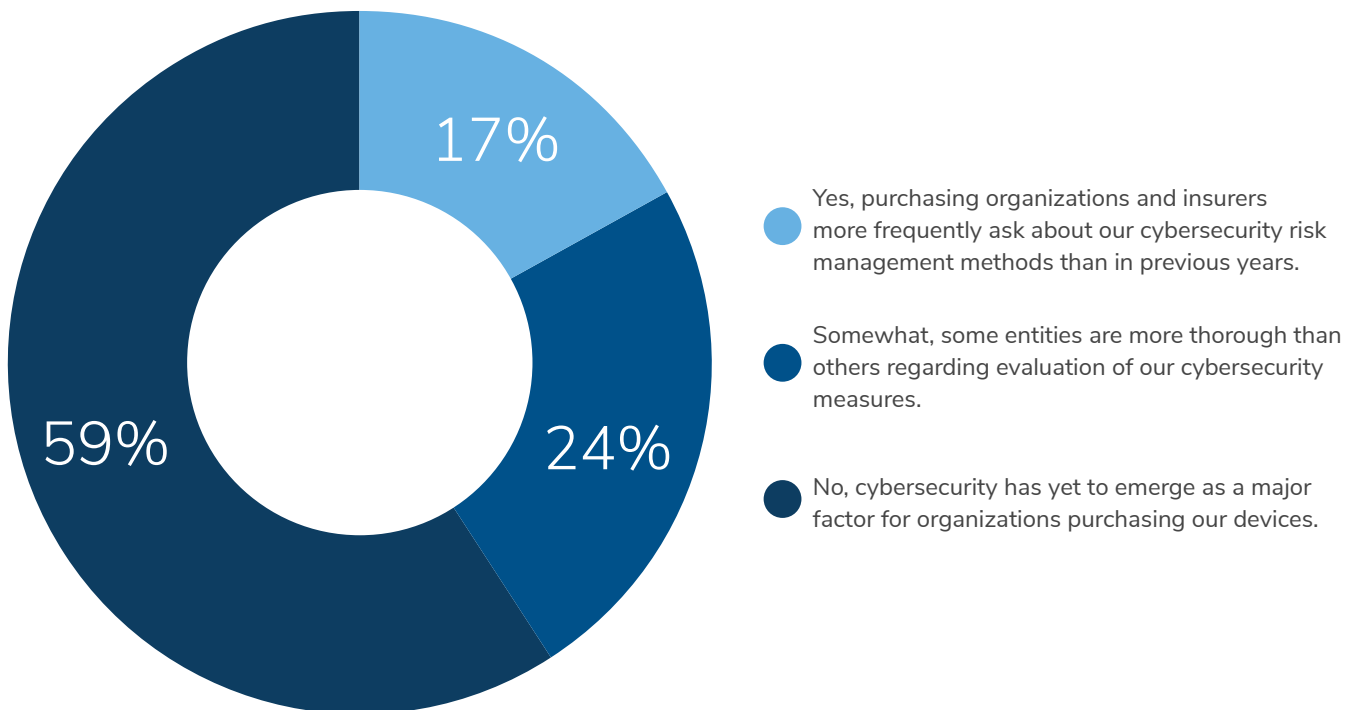
Overall, the number of companies reporting formal cybersecurity processes in place increased slightly in our 2021 results, up to 29% of firms compared to 26% in 2020. Larger firms are more likely to have implemented such processes, whereas a higher percentage of firms with fewer than 250 employees (about 40%) indicated no cybersecurity risk management processes in place because they do not produce Internet-connected devices.



Based on 450 responses.

## Have you experienced increased scrutiny from healthcare providers of your cybersecurity measures as part of these organizations' procurement and purchasing processes?

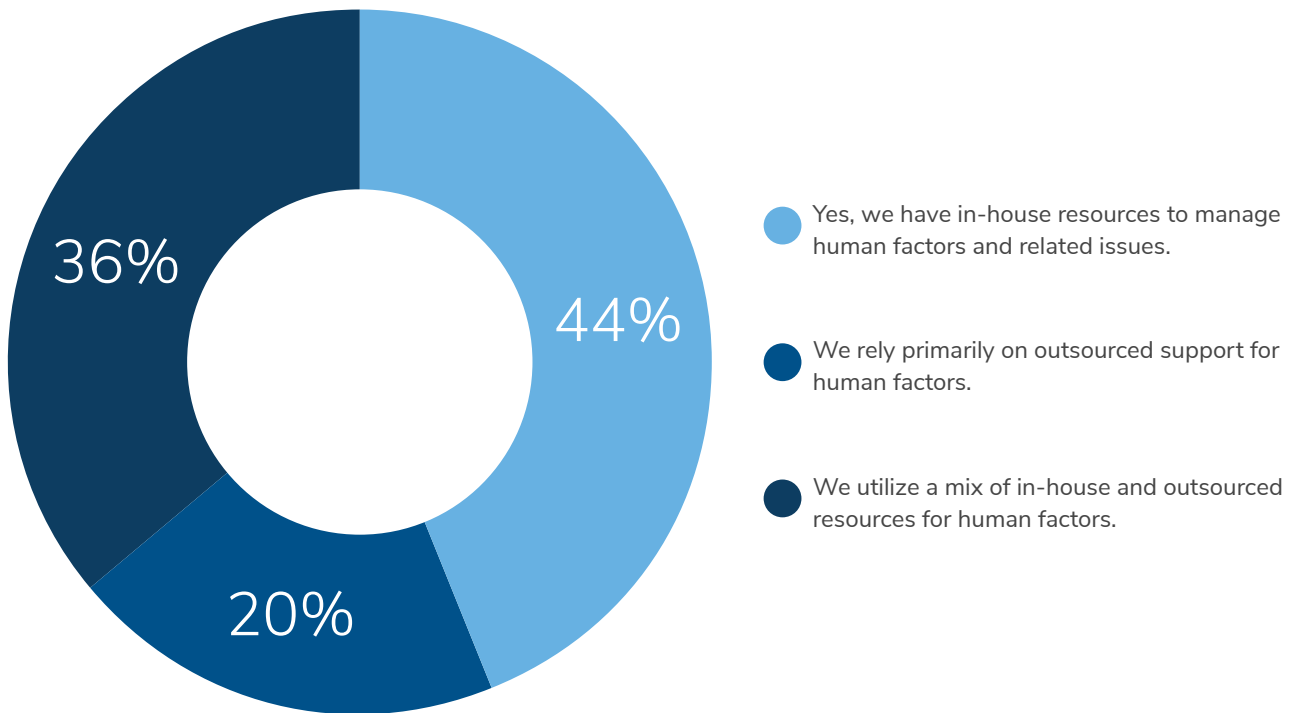
Our 2021 results found no significant changes in terms of how many respondents are having to demonstrate cybersecurity risk controls to healthcare delivery organizations or group purchasing organizations. Less than 20% of firms report having to disclose more information about their cybersecurity measures during purchasing and procurement processes; 32% of our largest respondents indicated more scrutiny from purchasing organizations this year, while roughly 60% of smaller firms reported no additional cybersecurity-related scrutiny in this regard.



Based on 428 responses.

## Do you maintain a core competency in human factors engineering?

In general, medical device and IVD manufacturers continue to rely on a mix of in-house and third-party resources for their human factors engineering (HFE) efforts, in line with our 2020 survey results. However, more large firms (56%) utilize internal HFE resources, according to our 2021 results, while smaller firms with fewer than 50 employees rely on external HFE resources at a slightly higher rate (40%) than their larger counterparts.



Based on 451 responses.

## Have you developed formal procedures for applying human factors engineering during your product development process?

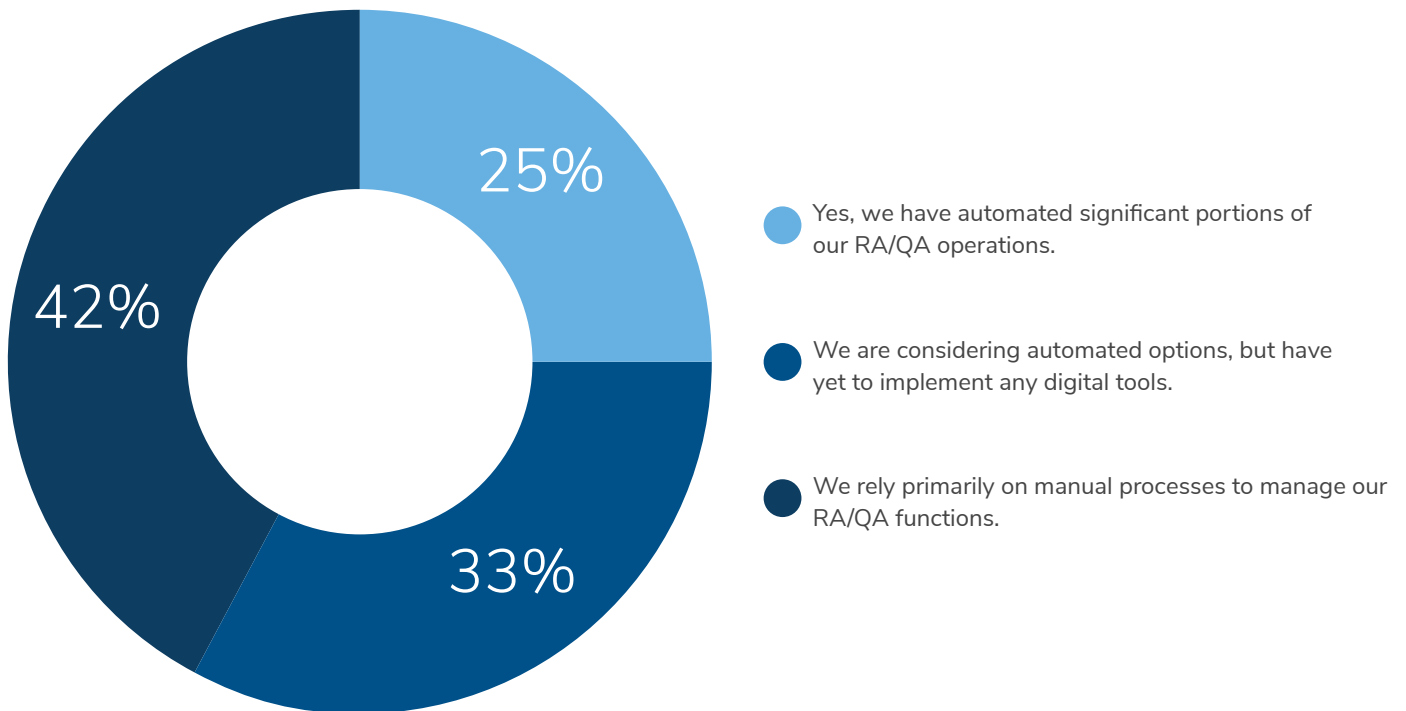
Two-thirds of our largest respondents indicated that they apply HFE processes and procedures early on in their product development cycles—up from 53% of large companies in our 2020 survey. Perhaps more notably, pluralities of respondents of all sizes reported utilizing HFE practices early in their product development processes, suggesting greater awareness across the industry that early-stage HFE can yield more effective and usable devices.

Number of Employees	Yes, we have procedure-based human factors components in place for product development.	We are in the process of establishing a human factors process for product development.	We have not yet established formal procedures for human factors within product development.
10-49	41%	22%	37%
50-249	52%	24%	24%
250-999	41%	31%	28%
1,000+	67%	21%	12%

Based on 452 responses.

## Have you considered automating components of your RA/QA process?

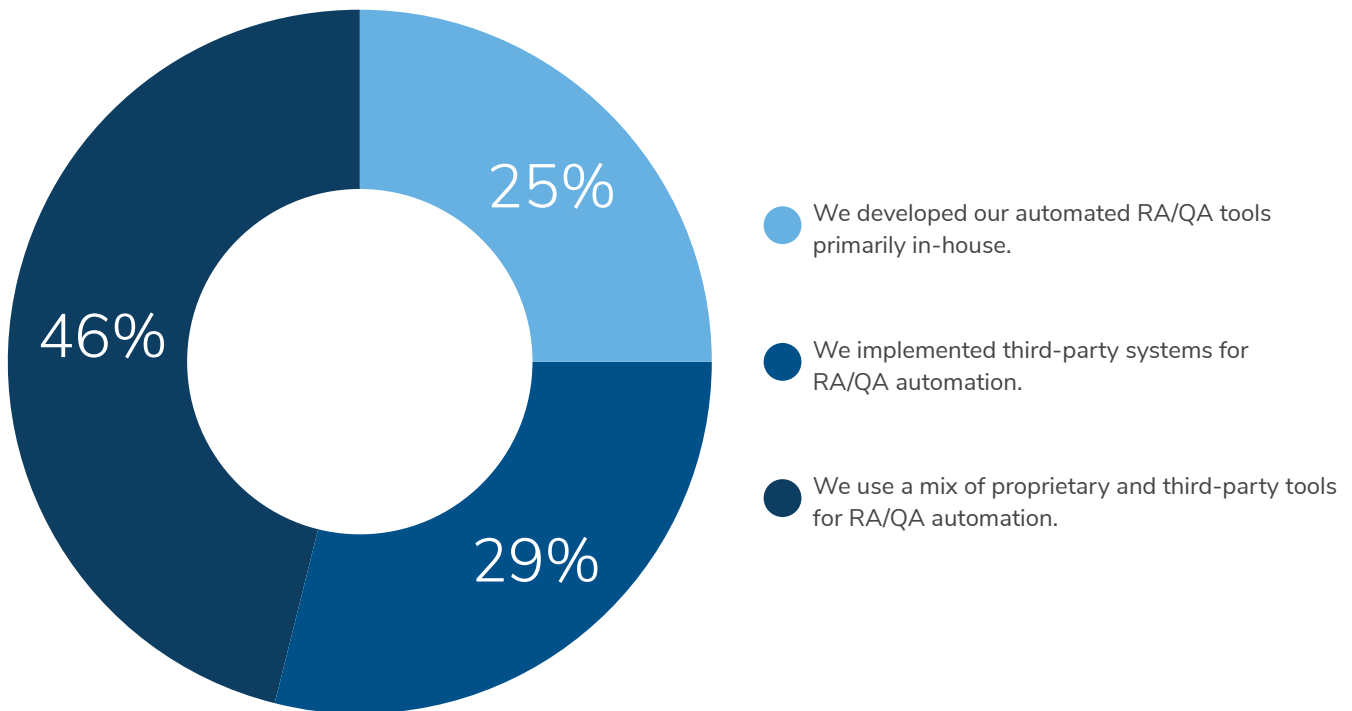
As in our 2020 survey, a majority of this year's respondents (nearly 60%) reported either that they have implemented automated RA/QA capabilities, or are considering these options. Roughly half of all larger firms have already begun using digital RA/QA software, whereas more than 40% of small companies rely on manual RA/QA tools with no immediate plans to consider automated support for these functions.



Based on 491 responses.

## If you use automated RA/QA tools, did you develop these digital capabilities in house or did you rely on third-party systems?

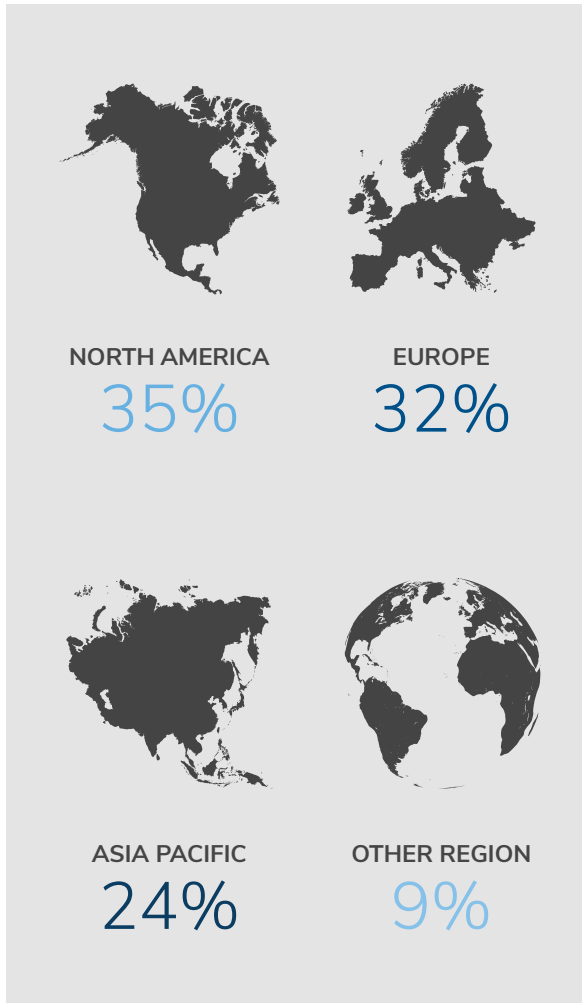
Our 2021 survey results showed a slight edge for third-party versus internally developed digital RA/QA tools, but most respondents (nearly 46%) continue preferring a mix of in-house and external technologies. Like our 2020 results, these preferences apply regardless of company size or location.



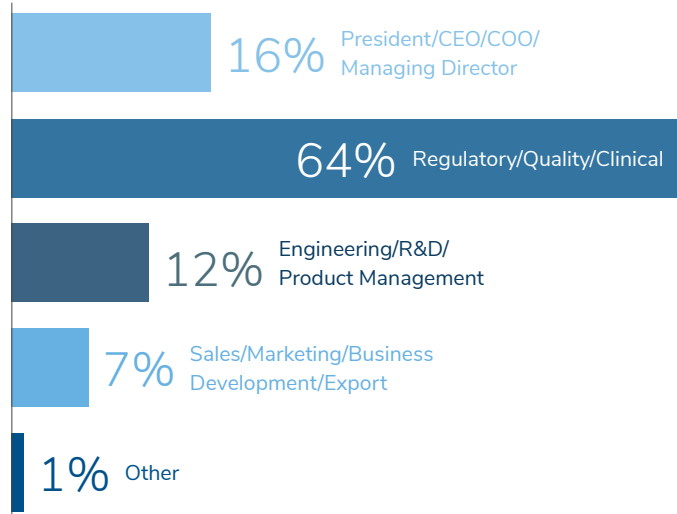
Based on 305 responses.

## Who took this survey?

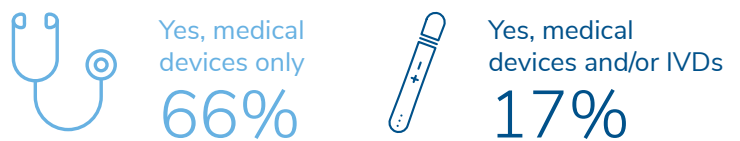
More than 1,670 people worldwide took our 2021 Medical Device Industry Outlook survey.



## What is your primary area of responsibility within your company?

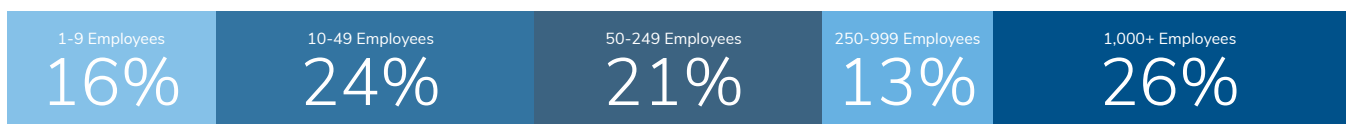


## Does your company design or manufacture medical devices or IVDs?



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

## How many people work for your organization?







# Survey Methodology

Our 2021 Global Medical Device Industry Outlook survey was conducted between January 7 and February 5, 2021. A total of 1,678 medical device and IVD industry professionals took part.

The survey was emailed to individuals in a database list maintained by EMERGO by UL, and 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 and IVD 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, RA/QA professionals make up a much higher percentage of respondents than otherwise represented in the industry. We excluded RA/QA respondents from some questions, but overall results should be interpreted with this in mind.

Our intention in conducting this survey is to provide a high-level snapshot of the industry's current state, 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 [emergomarketing@ul.com](mailto:emergomarketing@ul.com).